Exhibit 1

Department of Health and Human Services

In Re: Petition for Extension of Substantial Equivalence Report Deadline for Certain Premium Cigars, Pursuant to Section 319 of the Public Health Service Act, 42 U.S.C. § 247d(d).

[PROPOSED] ORDER

1. The nation and the world are currently struggling with a shared health emergency stemming from a global pandemic. On January 31, 2020, pursuant to Section 319 of the Public Health Service Act, codified at 42 U.S.C. § 247d, I declared a public health emergency due to the COVID-19 pandemic. On March 13, 2020, President Donald J. Trump declared a national emergency in response to the threat raised by the COVID-19 pandemic. Adopting Centers for Disease Control & Prevention guidelines, the President has urged all but the most essential employees to work from home to the extent possible and has further recommended that Americans not gather in any setting in groups of greater than 10 people. *See* Ctrs. for Disease Control & Prevention, *Coronavirus Disease 2019 (COVID-19) Situation Summary.* An increasing number of states and localities, including large states like California, New York and Pennsylvania, have issued "shelter in place" orders, requiring large segments of the population to remain at home and work from there, to the extent possible. *See, e.g.*, Executive Dep't, State of California, E.O. N-33-20 (Mar. 4, 2020), *available at* https://covid19.ca.gov/img/Executive-Order-N-33-20.pdf; Office of the Mayor, Dep't of Public Health, City of Philadelphia, *Emergency Order Temporarily Prohibiting Operation Of Non-Essential Businesses And Congregation Of Persons To Prevent The Spread Of 2019 Novel Corona Virus (Covid-19)*, Order N. 2 (Mar. 22, 2020), *available at* https://www.phila.gov/media/20200322130746/Order-2-Business-And-Congregation-Prohibition-Stay-At-Home.pdf; State of New York, Executive Chambers, E.O. 202.8 (Mar. 20, 2020), *available at* https://www.governor.ny.gov/news/no-

2028-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency. Americans have largely complied with the directives, recommendations and orders, slowing large segments of our economy.

2. This Order stems from the impact of this international, national and state health emergency on pending FDA deadlines for cigar manufacturers to submit pre-market "substantial equivalence" reports under the FDA's "deeming rule," which deemed cigars and other tobacco products to be subject to the Tobacco Control Act, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016), and thus to submit to the FDA certain reports before beginning or continuing to market their products, *see* Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. 111-31, 123 Stat. 1776 *et seq.*; Federal Food, Drug and Cosmetic Act §§ 905(j), 910 (21 U.S.C. §§ 387e(j), 387j). Absent the extension requested by petitioners, the deadline for premium cigar manufacturers to submit substantial equivalence reports for products commercially marketed for the first time between February 15, 2007 and August 8, 2016 is May 12, 2020. This Order is in response to the petition of several "premium cigar" manufacturers, including Petitioners Alec Bradley Cigar Distributors, Inc., Ashton Distributors, Inc., Holt Cigar Company, Inc., Crowned Heads, LLC, A. Fuente & Co., Piloto Cigars, Inc., Rocky Patel Premium Cigars, Oliva Cigar Co., Cigar Rights of America and its members, and the Premium Cigar Association and its members. Petitioners seek an extension of the deadline for submitting substantial equivalence reports for the premium cigar products of the corporate petitioners and the members of the association petitioners. For the limited purposes of this order, "premium cigars" are defined to

include any cigar that: (1) is wrapped in whole tobacco leaf; (2) contains 100 percent tobacco leaf binder; (3) contains primarily long filler tobacco; (4) is made by manually combining the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) does not have a characterizing flavor other than tobacco; and (7) weighs more than 6 pounds per 1000 units. For the above described products, petitioners request that the current deadline be extended for six months, until November 12, 2020. Petitioners have submitted a joint Petition for Stay of Action of Substantial Equivalence Report Deadline for Premium Cigars, requesting that HHS extend by 6 months the current May 12, 2020 Substantial Equivalence Report deadline. Section 319 of the Public Health Service Act, codified at 42 U.S.C. § 247d, authorizes the Secretary of HHS to extend deadlines for regulatory schemes under his supervision when regulated entities are "unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary" due to a public health emergency. 42 U.S.C. § 247d(d). The Secretary may grant such extensions "as the circumstances reasonably require." *Id.* The Secretary also "may waive . . . any sanctions otherwise applicable to such failure to comply." *Id.* § 247d(d). To extend any deadline or waive any sanction associated with missing a report deadline, the Secretary must determine that "individuals or public or private entities are unable to comply with" the relevant deadline "wholly or partially as a result of a public health emergency" declared by the Secretary. *Id.*

3. Petitioners have demonstrated that these criteria are met. As previously noted, on January 31, 2020, I declared a public health emergency, pursuant to 42 U.S.C. § 247d, due to the COVID-19 pandemic. This and other federal, state, and local government responses to the COVID-19 pandemic have had a substantial impact on American businesses generally, and Petitioners in particular. Businesses across the country have complied with federal Government

guidance, shutting their offices and factories, and in some jurisdictions, closing offices and factories is mandatory, as state and local governments have banned leaving homes except for essential purposes. *See, e.g.*, California Coronavirus Response, Coronavirus (COVID-19) in California (Mar. 19, 2020). It is likely that these state and local mandates will expand across the country, including in Pennsylvania, where petitioners Holt Cigar Company and Ashton Distributors' Pennsylvania offices were forced to close after the Governor ordered that all "non-life sustaining businesses" must close immediately. *See* Declaration of Nadia Trowbridge ¶ 4; Order of the Governor of the Commonwealth of Pennsylvania Regarding the Closure of All Businesses That Are Not Life Sustaining (Mar. 19, 2020), *available at* https://www.scribd.com/document/452416027/20200319-TWW-COVID-19-Business-Closure-Order.

4. Similarly, as manufacturers of premium cigars, Petitioners depend on operations for tobacco and assembly of their product in Honduras, Nicaragua and the Dominican Republic. *See* Declaration of Robert T. Brady ¶ 4; Declaration of Bernardo Rodriguez ¶ 4; Declaration of Rocky Patel ¶ 4. Government mandates have closed some of those operations, and others are expected to close to protect their employees from the pandemic. Declaration of Nadia Trowbridge at ¶ 4; Declaration of Rocky Patel at ¶¶ 4-5

5. These domestic and foreign closure of offices and factories are a problem because preparing substantial equivalence submissions for premium cigars includes work that cannot be performed remotely. It requires, for example, employees to physically compare applicant cigars to those on the market prior to 2007. *See* Declaration of Robert Brady ¶¶ 4-5.

6. On the basis of the foregoing, I find that the COVID-19 public health emergency, accompanying domestic and foreign government guidelines and mandates, and surrounding

economic decisions have rendered the petitioner corporations and the members of the petitioner associations "unable to comply with [the] deadline[ ] for submission of" substantial equivalence reports "to the Secretary." 42 U.S.C § 247d(d). I find that these "circumstances reasonably require" the May 12, 2020—with the scope and limitations set forth below—be extended for six months until November 12, 2020. *Id.* I also find that the "circumstances reasonably require" the waiver of "sanctions otherwise applicable to the failure to comply" with the substantial equivalence deadline as set forth below.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to 42 U.S.C. § 247d(d), that:

a. The Petition for Extension of Deadlines Pursuant to the Public Health Service Act, 42 U.S.C. § 247d(d), is GRANTED.

b. The pending May 12, 2020 deadline for substantial equivalence reports required as a result of the Final Deeming Rule is extended until November 12, 2020, for any "premium cigars" sold by the petitioner corporations and the members of the petitioner associations.

c. In addition, any sanctions otherwise applicable to failure of the petitioner corporations and members of the petitioner associations to comply with requirements to submit substantial equivalence reports for those products that are within the scope of this extension. Those sanctions would include any fines or penalties or provisions of law that would render products for which such reports have not been submitted eligible to be considered "adulterated" under Section 902, "misbranded" under Section 903, or for "recall" pursuant to Section 908(c). *See* Act §§ 902 (21 U.S.C. § 387b), 903 (21 U.S.C. § 387c), 908(c) (21 U.S.C. § 387h(c)).

d. For purposes of this Order, "premium cigars" are defined as a cigar that: (1) is wrapped in whole tobacco leaf; (2) contains 100 percent tobacco leaf binder; (3) contains primarily long filler tobacco; (4) is made by manually combining the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) does not have a characterizing flavor other than tobacco; and (7) weighs more than 6 pounds per 1000 units.

e. This Order applies only to premium cigars that entered the market between February 15, 2007 and August 8, 2016.

SO ORDERED.

Dated: _____

_____
ALEX M. AZAR II
Secretary

Exhibit 2

Food and Drug Administration

In Re: Petition for Stay of Action of Substantial Equivalence Report Deadline for Premium Cigars, Required as a Result of the Final Deeming Rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016)

To Be Filed in Docket Nos. FDA-2014-N-0189, FDA-2016-N-3818, FDA-2017-D-2834, FDA-2017-N-6107, and FDA-2019-D-0661

[PROPOSED] ORDER

1. The nation and the world are currently struggling with a shared health emergency stemming from a global pandemic. On January 31, 2020, pursuant to Section 319 of the Public Health Service Act, codified at 42 U.S.C. § 247d, Secretary of Health and Human Services Alex Azar declared a public health emergency due to the COVID-19 pandemic. On March 13, 2020, President Donald J. Trump declared a national emergency in response to the threat raised by the COVID-19 pandemic. Adopting Centers for Disease Control & Prevention guidelines, the President has urged all but the most essential employees to work from home to the extent possible and has further recommended that Americans not gather in any setting in groups of greater than 10 people. *See* Ctrs. for Disease Control & Prevention, *Coronavirus Disease 2019 (COVID-19) Situation Summary.* An increasing number of states and localities, including large states like California, New York and Pennsylvania, have issued "shelter in place" orders, requiring large segments of the population to remain at home and work from there, to the extent possible. *See, e.g.* Executive Dep't, State of California, E.O. N-33-20 (Mar. 4, 2020), *available at* https://covid19.ca.gov/img/Executive-Order-N-33-20.pdf; Office of the Mayor, Dep't of Public Health, City of Philadelphia, *Emergency Order Temporarily Prohibiting Operation Of Non-Essential Businesses And Congregation Of Persons To Prevent The Spread Of 2019 Novel Corona*

Virus (Covid-19), Order N. 2 (Mar. 22, 2020), *available at* https://www.phila.gov/media/20200322130746/Order-2-Business-And-Congregation-Prohibition-Stay-At-Home.pdf; State of New York, Executive Chambers, E.O. 202.8 (Mar. 20, 2020), *available at* https://www.governor.ny.gov/news/no-2028-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency. Americans have largely complied with the directives, recommendations and orders, slowing large segments of our economy.

2. This order stems from the impact of this international, national and state health emergency on pending FDA deadlines for premium cigar manufacturers to submit pre-market "substantial equivalence" reports under the FDA's "deeming rule," which deemed cigars and other tobacco products to be subject to the Tobacco Control Act, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016), and thus to submit to the FDA certain reports before beginning or continuing to market their products, *see* Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. 111-31, 123 Stat. 1776 *et seq.*; Federal Food, Drug and Cosmetic Act §§ 905(j), 910 (21 U.S.C. §§ 387e(j), 387j). Absent action on this petition, the deadline for premium cigar manufacturers to submit substantial equivalence reports for products commercially marketed for the first time between February 15, 2007 and August 8, 2016 is May 12, 2020.

3. This Order is in response to the petition of several "premium cigar" manufacturers, including Petitioners Alec Bradley Cigar Distributors, Inc., Ashton Distributors, Inc., Holt Cigar Company, Inc., Crowned Heads, LLC, A. Fuente & Co., Piloto Cigars, Inc., Rocky Patel Premium Cigars, Oliva Cigar Co., Cigar Rights of America and its members, and the Premium Cigar

Association and its members. Petitioners seek an extension of the deadline for submitting substantial equivalence reports for the premium cigar products of the corporate petitioners and the members of the association petitioners. For the limited purposes of this order, "premium cigars" are defined as any cigar that: (1) is wrapped in whole tobacco leaf; (2) contains 100 percent tobacco leaf binder; (3) contains primarily long filler tobacco; (4) is made by manually combining the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) does not have a characterizing flavor other than tobacco; and (7) weighs more than 6 pounds per 1000 units. For the above described products, petitioners request that the current deadline be extended for six months, until November 12, 2020.

4. Petitioners have established good cause for the stay they seek. The current government response to the COVID-19 pandemic has had a substantial impact on American businesses generally, and petitioners in particular. Businesses across the country have complied with federal Government guidance, shutting their offices and factories, and in some jurisdictions, closing offices and factories is mandatory, as state and local governments have banned leaving homes except for essential purposes. *See, e.g.*, California Coronavirus Response, *Coronavirus (COVID-19) in California* (Mar. 19, 2020). It is likely that these state and local mandates will expand across the country, including in Pennsylvania, where petitioners Holt Cigar Company and Ashton Distributors' Pennsylvania offices were forced to close after the Governor ordered that all "non-life sustaining businesses" must close immediately. *See* Declaration of Nadia Trowbridge ¶ 4; Order of the Governor of the Commonwealth of Pennsylvania Regarding the Closure of All Businesses That Are Not Life Sustaining (Mar. 19, 2020), *available at* https://www.scribd.com/document/452416027/20200319-TWW-COVID-19-Business-Closure-Order.

5. Similarly, as manufacturers of premium cigars, Petitioners depend on operations for tobacco and assembly of their product in Honduras, Nicaragua and the Dominican Republic. *See* Declaration of Robert T. Brady ¶ 4; Declaration of Bernardo Rodriguez ¶ 4; Declaration of Rocky Patel ¶ 4. Government mandates have closed some of those operations, and others are expected to close to protect their employees from the pandemic. Declaration of Nadia Trowbridge at ¶ 4; Declaration of Rocky Patel at ¶¶ 4-5

6. These U.S. and foreign government actions have rendered compliance with the FDA's May 12, 2020 substantial equivalence report impracticable and unduly burdensome. The premium cigar industry, which is comprised of small, family-owned businesses with few employees, is unable to meet the substantial equivalence deadline under these circumstances. Preparing substantial equivalence submissions for premium cigars is labor intensive and includes work that cannot be performed remotely; it requires, for example, employees to physically compare applicant cigars to those on the market prior to 2007. *See* Declaration of Robert Brady ¶¶ 4-5.

7. Granting a stay will not raise countervailing issues of public health that will outweigh the economic hardship caused by requiring Petitioners to meet the May 12, 2020 deadline during the COVID-19 pandemic. *See* 21 C.F.R. § 10.35(e)(4). As noted, the FDA already has determined that premium cigars will be their lowest priority for enforcement, even after May 12, 2020. FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (Jan. 2020) at 31. Therein, agency based this determination on premium cigars "comparatively low rates of youth use." *Id.* They also constitute a relatively small portion of the market for tobacco products.

8. I also find that the petition meets the requirements for a mandatory stay under 21 C.F.R. § 10.35(e). **First**, the corporate petitioners and the members of the association petitioners clearly will suffer irreparable harm. The COVID crisis renders compliance with the May 12, 2020 deadline impossible. And enforcement of the substantial equivalence filing deadline will lead cigar manufacturers to cease sales of their product, and in many cases, close their businesses, thousands more to lose their jobs at a time when the economy can scarcely afford further job losses. Petitioners lack an economic judicial remedy for those economic losses. **Second**, to the extent that pending litigation is a factor triggering a mandatory stay, the petitioner associations are maintaining lawsuits against the FDA challenging the substantial equivalence process, in which there is a pending motion for summary judgment. *Cigar Ass'n. of Am. v. U.S. Food & Drug Admin.*, No. 16-cv-1460 (D.D.C.), ECF Nos. 178, 180, 185-86, 188. **Third**, "there are sound public policy grounds supporting [a] stay." 21 C.F.R. § 10.35(e)(3). In the absence of a stay, it will be nearly impossible for premium cigar manufacturers to comply with the May 12, 2020 deadline. The result will be massive and entirely avoidable economic displacement, on top of that caused directly by the COVID crisis. *Id.* Other agencies have recognized this reality, relaxing and extending regulatory reporting deadlines. **Fourth**, "the delay resulting from the stay is not outweighed by public health other public interests." 21 C.F.R. § 10.35(e)(4). This agency already has determined that premium cigars will be their lowest priority for enforcement. A stay—limited to premium cigar products—will not raise countervailing issues of public health that will outweigh the economic distress caused by the combination of the May 12 deadline and the COVID crisis.

9. I find that the petition is timely, even though it was filed later than 30 days after the date of the decision involved. 21 C.F.R. § 10.35(b), (g). The COVID-19 crisis was not extant

within the 30 days after the decisions involved. The intervention of the COVID-19 crisis is good cause for accepting and granting the petition more than 30 days after the decisions involved.

NOW, THEREFORE, IT IS HEREBY ORDERED, pursuant to 21 C.F.R. § 10.35(b), that:

a. The Petition for Stay of Action is GRANTED.

b. The pending May 12, 2020 deadline for substantial equivalence reports is stayed until November 12, 2020 as to all "premium cigars" sold by the petitioner corporations and the members of the petitioner associations.

c. For purposes of this Order, "premium cigars" are defined as a cigar that: (1) is wrapped in whole tobacco leaf; (2) contains 100 percent tobacco leaf binder; (3) contains primarily long filler tobacco; (4) is made by manually combining the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) does not have a characterizing flavor other than tobacco; and (7) weighs more than 6 pounds per 1000 units.

d. This Order applies only to premium cigars that entered the market between February 15, 2007 and August 8, 2016.

SO ORDERED.

Dated: _____

_____

STEPHEN M. HAHN
Commissioner

Exhibit 3

Part III - Administrative, Procedural, and Miscellaneous

Relief for Taxpayers Affected by Ongoing Coronavirus Disease 2019 Pandemic

Notice 2020-17

I. PURPOSE

On March 13, 2020, the President of the United States issued an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act in response to the ongoing Coronavirus Disease 2019 (COVID-19) pandemic (Emergency Declaration). The Emergency Declaration instructed the Secretary of the Treasury "to provide relief from tax deadlines to Americans who have been adversely affected by the COVID-19 emergency, as appropriate, pursuant to 26 U.S.C. 7508A(a)." Pursuant to the Emergency Declaration, this notice provides relief under section 7508A(a) of the Internal Revenue Code for the persons described in section III of this notice that the Secretary of the Treasury has determined to be affected by the COVID-19 emergency.

II. BACKGROUND

Section 7508A provides the Secretary of the Treasury or his delegate (Secretary) with authority to postpone the time for performing certain acts under the internal revenue laws for a taxpayer determined by the Secretary to be affected by a Federally declared disaster as defined in section 165(i)(5)(A). Pursuant to section 7508A(a), a

period of up to one year may be disregarded in determining whether the performance of certain acts is timely under the internal revenue laws.

III. GRANT OF RELIEF

The Secretary has determined that any person with a Federal income tax payment due April 15, 2020, is affected by the COVID-19 emergency for purposes of the relief described in this section III (Affected Taxpayer).

For an Affected Taxpayer, the due date for making Federal income tax payments due April 15, 2020, in an aggregate amount up to the Applicable Postponed Payment Amount, is postponed to July 15, 2020. The Applicable Postponed Payment Amount is up to $10,000,000 for each consolidated group (as defined in §1.1502-1) or for each C corporation that does not join in filing a consolidated return. For all other Affected Taxpayers, the Applicable Postponed Payment Amount is up to $1,000,000 regardless of filing status. For example, the Applicable Postponed Payment Amount is the same for a single individual and for married individuals filing a joint return. In both instances the Applicable Postponed Payment Amount is up to $1,000,000.

The relief provided in this section III is available solely with respect to Federal income tax payments (including payments of tax on self-employment income) due on April 15, 2020, in respect of an Affected Taxpayer's 2019 taxable year, and Federal estimated income tax payments (including payments of tax on self-employment income) due on April 15, 2020, for an Affected Taxpayer's 2020 taxable year. The Applicable Postponed Payment Amounts described in this section III include, in the aggregate, all

payments described in the preceding sentence due on April 15, 2020 for such Affected Taxpayers.

No extension is provided in this notice for the payment or deposit of any other type of Federal tax, or for the filing of any tax return or information return.

As a result of the postponement of the due date for making Federal income tax payments up to the Applicable Postponed Payment Amount from April 15, 2020, to July 15, 2020, the period beginning on April 15, 2020, and ending on July 15, 2020, will be disregarded in the calculation of any interest, penalty, or addition to tax for failure to pay the Federal income taxes postponed by this notice. Interest, penalties, and additions to tax with respect to such postponed Federal income tax payments will begin to accrue on July 16, 2020. In addition, interest, penalties and additions to tax will accrue, without any suspension or deferral, on the amount of any Federal income tax payments in excess of the Applicable Postponed Payment Amount due but not paid by an Affected Taxpayer on April 15, 2020.

Affected Taxpayers subject to penalties or additions to tax despite the relief granted by this section III may seek reasonable cause relief under section 6651 for a failure to pay tax or seek a waiver to a penalty under section 6654 for a failure by an individual or certain trusts and estates to pay estimated income tax, as applicable. Similar relief with respect to estimated tax payments is not available for corporate taxpayers or tax-exempt organizations under section 6655.

IV. DRAFTING INFORMATION

The principal author of this notice is Jennifer Auchterlonie of the Office of Associate Chief Counsel, Procedure and Administration. For further information regarding this notice, you may call (202) 317-3400 (not a toll-free call).

Exhibit 4

Part III - Administrative, Procedural, and Miscellaneous

Relief for Taxpayers Affected by Ongoing Coronavirus Disease 2019 Pandemic

Notice 2020-18

I. PURPOSE

On March 13, 2020, the President of the United States issued an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act in response to the ongoing Coronavirus Disease 2019 (COVID-19) pandemic (Emergency Declaration). The Emergency Declaration instructed the Secretary of the Treasury "to provide relief from tax deadlines to Americans who have been adversely affected by the COVID-19 emergency, as appropriate, pursuant to 26 U.S.C. 7508A(a)." Pursuant to the Emergency Declaration, this notice provides relief under section 7508A(a) of the Internal Revenue Code (Code) for the persons described in section III of this notice that the Secretary of the Treasury has determined to be affected by the COVID-19 emergency. This notice supersedes Notice 2020-17.

II. BACKGROUND

Section 7508A provides the Secretary of the Treasury or his delegate (Secretary) with authority to postpone the time for performing certain acts under the internal revenue laws for a taxpayer determined by the Secretary to be affected by a Federally declared disaster as defined in section 165(i)(5)(A). Pursuant to section 7508A(a), a

period of up to one year may be disregarded in determining whether the performance of certain acts is timely under the internal revenue laws.

On March 18, 2020, the Department of the Treasury and the Internal Revenue Service issued Notice 2020-17 providing relief under section 7508A(a) of the Code, which postponed the due date for certain Federal income tax payments from April 15, 2020 until July 15, 2020. This notice restates and expands upon the relief provided in Notice 2020-17.

III. GRANT OF RELIEF

The Secretary of the Treasury has determined that any person with a Federal income tax payment or a Federal income tax return due April 15, 2020, is affected by the COVID-19 emergency for purposes of the relief described in this section III (Affected Taxpayer). The term "person" includes an individual, a trust, estate, partnership, association, company or corporation, as provided in section 7701(a)(1) of the Code.

For an Affected Taxpayer, the due date for filing Federal income tax returns and making Federal income tax payments due April 15, 2020, is automatically postponed to July 15, 2020. Affected Taxpayers do not have to file Forms 4868 or 7004. There is no limitation on the amount of the payment that may be postponed.

The relief provided in this section III is available solely with respect to Federal income tax payments (including payments of tax on self-employment income) and Federal income tax returns due on April 15, 2020, in respect of an Affected Taxpayer's 2019 taxable year, and Federal estimated income tax payments (including payments of

tax on self-employment income) due on April 15, 2020, for an Affected Taxpayer's 2020 taxable year.

No extension is provided in this notice for the payment or deposit of any other type of Federal tax, or for the filing of any Federal information return.

As a result of the postponement of the due date for filing Federal income tax returns and making Federal income tax payments from April 15, 2020, to July 15, 2020, the period beginning on April 15, 2020, and ending on July 15, 2020, will be disregarded in the calculation of any interest, penalty, or addition to tax for failure to file the Federal income tax returns or to pay the Federal income taxes postponed by this notice. Interest, penalties, and additions to tax with respect to such postponed Federal income tax filings and payments will begin to accrue on July 16, 2020.

IV. EFFECT ON OTHER DOCUMENTS

This Notice supersedes Notice 2020-17. Because of the expansion of relief provided in this notice and the fact that Notice 2020-17 is superseded, any phone calls regarding Notice 2020-17 that have not already been returned will not be returned. As noted below, taxpayers with questions regarding the application of this notice should contact (202) 317-5436.

V. DRAFTING INFORMATION

The principal author of this notice is Jennifer Auchterlonie of the Office of Associate Chief Counsel, Procedure and Administration. For further information regarding this notice, you may call (202) 317-5436 (not a toll-free call).

Exhibit 5

SECURITIES AND EXCHANGE COMMISSION

SECURITIES EXCHANGE ACT OF 1934
Release No. 34-88318 / March 4, 2020

ORDER UNDER SECTION 36 OF THE SECURITIES EXCHANGE ACT OF 1934 GRANTING EXEMPTIONS FROM SPECIFIED PROVISIONS OF THE EXCHANGE ACT AND CERTAIN RULES THEREUNDER

The current outbreak of coronavirus disease 2019 (COVID-19) was first reported on December 31, 2019 in Wuhan, China. The staff understands from entities and their representatives that COVID-19 may present challenges in timely meeting certain of their obligations under the federal securities laws. These entities may include U.S. companies with significant operations in the affected areas, as well as companies located in those regions. In light of this, we are issuing this Order to assist affected entities with meeting their obligations under the federal securities laws.

Section 36 of the Exchange Act authorizes the Commission, by rule, regulation, or order, to exempt, either conditionally or unconditionally, any person, security or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of the Exchange Act or any rule or regulation thereunder, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.

Any registrant or other person in need of additional assistance related to deadlines, delivery obligations or their public filings, should contact the Division of Corporation Finance at (202) 551-3500 or at https://tts.sec.gov/cgi-bin/corp_fin_interpretive.

I. TIME PERIOD FOR THE RELIEF

The time period for the relief specified in Sections II of this Order is as follows:

- With respect to those registrants or other persons impacted by COVID-19, the period from and including March 1, 2020 to April 30, 2020.
- The Commission intends to monitor the current situation and may, if necessary, extend the time period during which this relief applies, with any additional conditions the Commission deems appropriate and/or issue other relief.

II. FILING REQUIREMENTS FOR REGISTRANTS AND OTHER PERSONS

Disruptions to transportation, and limited access to facilities, support staff, and professional advisors as a result of COVID-19, could hamper the efforts of public companies and other persons with filing obligations to meet their filing deadlines. At the same time, investors have an interest in the timely availability of required information about these companies and the activities of persons required to file schedules and reports with respect to these companies. While the Commission believes that the relief from filing requirements provided by the exemption below is necessary and appropriate in the public interest and consistent with the protection of investors, we remind public companies and other persons who are the subjects of this Order to continue to evaluate their obligations to make materially accurate and complete disclosures in accordance with the federal securities laws.

Accordingly, IT IS ORDERED, pursuant to Section 36 of the Exchange Act, that a registrant (as defined in Exchange Act Rule 12b-2) subject to the reporting requirements of Exchange Act Section 13(a) or 15(d), and any person required to make any filings with respect to such a registrant, is exempt from any requirement to file or furnish materials with the Commission under Exchange Act Sections 13(a), 13(f), 13(g), 14(a), 14(c), 14(f), 15(d) and Regulations 13A, Regulation 13D-G (except for those provisions mandating the filing of Schedule 13D or amendments to Schedule 13D), 14A, 14C and 15D, and Exchange Act Rules 13f-1, and 14f-1, as applicable, where the conditions below are satisfied.

Conditions.

(a) The registrant or any person required to make any filings with respect to such a registrant is unable to meet a filing deadline due to circumstances related to COVID-19;

(b) Any registrant relying on this Order furnishes to the Commission a Form 8-K or, if eligible, a Form 6-K by the later of March 16 or original filing deadline of the report[1] stating:[2]

(1) that it is relying on this Order;

(2) a brief description of the reasons why it could not file such report, schedule or form on a timely basis;

(3) the estimated date by which the report, schedule, or form is expected to be filed;

[1] Any registrant relying on this Order would not need file a Form 12b-25 so long as the report, schedule, or form is filed within the time period prescribed by this Order.

[2] The Commission believes such statements, as furnished, to the extent they contain "forward-looking statements," would be subject to the safe harbor under Exchange Act, Section 21E. See the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 77z-1 (1998).

(4) if appropriate, a risk factor explaining, if material, the impact of COVID-19 on its business; and

(5) if the reason the subject report cannot be filed timely relates to the inability of any person, other than the registrant, to furnish any required opinion, report or certification, the Form 8-K or Form 6-K shall have attached as an exhibit a statement signed by such person stating the specific reasons why such person is unable to furnish the required opinion, report or certification on or before the date such report must be filed.

(c) The registrant or any person required to make any filings with respect to such a registrant files with the Commission any report, schedule, or form required to be filed no later than 45 days after the original due date; and

(d) In any report, schedule or form filed by the applicable deadline pursuant to paragraph (c) above, the registrant or any person required to make any filings with respect to such a registrant must disclose that it is relying on this Order and state the reasons why it could not file such report, schedule or form on a timely basis.

III. FURNISHING OF PROXY AND INFORMATION STATEMENTS

We also believe that relief is warranted for those seeking to comply with the requirements of Exchange Act Sections 14(a) and (c) and Regulations 14A and 14C and Exchange Act Rule 14f-1 thereunder to furnish materials to security holders when mail delivery is not possible and that the following exemption is necessary and appropriate in the public interest and consistent with the protection of investors.

Accordingly, IT IS ORDERED, pursuant to Section 36 of the Exchange Act, that a registrant or any other person is exempt from the requirements of the Exchange Act and the rules thereunder to furnish proxy statements, annual reports, and other soliciting materials, as applicable (the "Soliciting Materials"), and the requirements of the Exchange Act and the rules thereunder to furnish information statements and annual reports, as applicable (the "Information Materials"), where the conditions below are satisfied.

Conditions.

(a) The registrant's security holder has a mailing address located in an area where, as a result of COVID-19, the common carrier has suspended delivery service of the type or class customarily used by the registrant or other person making the solicitation; and

(b) The registrant or other person making a solicitation has made a good faith effort to furnish the Soliciting Materials to the security holder, as required by the rules applicable to the particular method of delivering Soliciting Materials to the security holder, or, in the case of Information Materials, the registrant has made a good faith effort to furnish the Information Materials to the security holder in accordance with the rules applicable to Information Materials.

By the Commission.

Vanessa A. Countryman
Secretary

Exhibit 6

UNITED STATES OF AMERICA
FEDERAL ENERGY REGULATORY COMMISSION

Extension of Non-Statutory Deadlines — Docket No. AD20-11-000

NOTICE GRANTING EXTENSION OF TIME

(March 19, 2020)

On March 13, 2020, the President issued a proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19). Regulated entities have taken steps to protect the health and safety of their employees and the public, and to help mitigate or slow the transmission of the coronavirus within their communities. In recognition of the potential impact these steps may have on meeting regulatory requirements, pursuant to sections 385.101(e) and 385.2008 of the Commission's Rules of Practice and Procedure, 18 C.F.R. §§ 385.101(e) and 385.2008 (2019), there is good cause to extend until May 1, 2020 the following deadlines for filings required by the Commission that occur on or before May 1, 2020 for those entities that are unable to meet deadlines due to steps they have taken to meet the emergency conditions: (1) the deadline for filing forms required by the Commission, with the exception of the FERC Form No. 6, Annual Report of Oil Pipeline Companies;[1] (2) the deadline for entities to make other non-statutory filings required by the Commission (e.g., compliance filings, responses to deficiency letters, rulemaking comments); and (3) the deadline for entities to make filings required by their tariffs or rate schedules.[2]

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[1] Due to the upcoming Five-Year Review of the Oil Pipeline Index and the need for the Form No. 6 to begin this review, the deadline for filing that form remains April 18, 2020, as provided in 18 C.F.R. § 357.2(b)(2). Because April 18, 2020, is a Saturday, oil pipelines must file the Form No. 6 by Monday, April 20, 2020, consistent with 18 C.F.R. § 385.2007(a)(2).

[2] There are several pending uncontested motions in individual Commission proceedings seeking an extension of time to submit these required filings. This Notice also grants those pending uncontested motions for an extension of time until May 1, 2020 to submit the required filings in those proceedings.

The Commission's regulations allow for extension of other types of filings. Entities seeking extensions of other deadlines (e.g., deadlines for filing interventions or protests, filing answers), as well as further extensions for the required filings identified above, may file motions seeking extensions in such proceedings, as appropriate. In addition, entities may seek waiver of the Commission's orders, regulations, tariffs and rate schedules, as appropriate, to address needs resulting from steps they have taken in response to the coronavirus.[3] Those requests may include motions for waiver of the Commission's regulations that govern the form of filings.[4] Action on all such motions will be taken as expeditiously as possible.

Kimberly D. Bose,
Secretary.

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[3] *See, e.g. Sierra Pacific Power Company, Nevada Power Company*, 170 FERC ¶ 61,236 (2020).

[4] For example, Commission regulations require certain filings be supported by a sworn declaration, and we recognize that steps a utility has taken to address the coronavirus may prevent the filing from containing such a declaration. *See, e.g.*, 18 CFR § 45.7 (2019).

Exhibit 7

(ORDER LIST: 589 U.S.)

THURSDAY, MARCH 19, 2020

ORDER

In light of the ongoing public health concerns relating to COVID-19, the following shall apply to cases prior to a ruling on a petition for a writ of certiorari:

IT IS ORDERED that the deadline to file any petition for a writ of certiorari due on or after the date of this order is extended to 150 days from the date of the lower court judgment, order denying discretionary review, or order denying a timely petition for rehearing. See Rules 13.1 and 13.3.

IT IS FURTHER ORDERED that motions for extensions of time pursuant to Rule 30.4 will ordinarily be granted by the Clerk as a matter of course if the grounds for the application are difficulties relating to COVID-19 and if the length of the extension requested is reasonable under the circumstances. Such motions should indicate whether the opposing party has an objection.

IT IS FURTHER ORDERED that, notwithstanding Rules 15.5 and 15.6, the Clerk will entertain motions to delay distribution of a petition for writ of certiorari where the grounds for the motion are that the petitioner needs additional time to file a reply due to difficulties relating to COVID-19. Such motions will ordinarily be granted by the Clerk as a matter of course if the length of the extension requested is reasonable under the circumstances and if the motion is actually received by the Clerk at least two days prior to the relevant distribution date. Such motions should indicate whether the opposing party has an objection.

IT IS FURTHER ORDERED that these modifications to the Court's Rules and practices do not apply to cases in which certiorari has been granted or a direct appeal or original action has been set for argument.

These modifications will remain in effect until further order of the Court.

Exhibit 8

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
AMENDED GENERAL ORDER 20-0012

March 17, 2020

IN RE: CORONAVIRUS COVID-19 PUBLIC EMERGENCY

In response to the COVID-19 public emergency, the Centers for Disease Control and Prevention has issued guidance recommending against mass gatherings of 50 or more persons for the next eight weeks (from March 15, 2020 through May 3, 2020). This impacts the ability of the Court to convene jury trials because jury-panel members initially report to a single location in the Jury Department. Also, the State of Illinois has closed Illinois schools until at least through March 30, 2020, and the Illinois Department of Public Health has recommended that the public implement social-distancing measures. In light of these public-health concerns, it is hereby ORDERED:

General Order 20-0012, entered on March 16, 2020, is vacated and replaced with this Amended General Order. To protect public health, reduce the size of public gatherings, and reduce any non-essential travel, the United States District Court for the Northern District of Illinois hereby orders, effective March 17, 2020:

1. In all civil cases, all deadlines, whether set by the court or by the Rules of Civil Procedure or Local Rules, are hereby extended by 21 days from the current deadline set. This also includes dates set by the Executive Committee in proceedings set before that Committee. The United States District Court remains accessible via electronic filing, and, in emergency situations and where resources permit, phone conferencing and video conferencing.
2. Civil case hearings, trials, and settlement conferences scheduled from March 17, 2020 until April 3, 2020 are stricken from the calendar, to be re-set by the presiding judge on or after April 6, 2020. The parties are cautioned that this Amended General Order does **not** affect the rights to or deadlines concerning any **appeal** from any decision of this Court. That is, the deadlines for filing a notice of appeal remain in place and must be followed to preserve appellate rights. The Court invites parties to file an extension of time to appeal under Appellate Rule 4(a)(5)(A) no later than 30 days after the time

prescribed by Rule 4(a). If a timely extension motion is filed, then the Court deems that good cause exists for the extension in light of current public-health concerns.

3. The Court recognizes and respects the right of criminal defendants to a speedy and public trial under the Sixth Amendment, particularly as to defendants detained pending trial. Therefore, the following procedures shall be implemented in criminal case proceedings:

    a) all criminal case proceedings, whether in the Eastern or Western Division, that cannot be continued will be conducted in the Eastern Division by emergency district judges as designated by the Chief Judge;

    b) Grand juries shall continue to meet during the week of March 16, 2020, as provided in General Order 20-0012. The Court will impose reasonable limits on grand jury meetings thereafter in consultation with the U.S. Attorney's Office;

    c) Judges may review complaints, applications for search warrants or trap/trace/pen registers, applications for wire taps, or applications for other such warrants or orders by reliable electronic means, rather than in person, under Criminal Rule 4.1;

    d) When practicable and with the defendant's written consent, initial appearances and arraignments may be conducted by video conference under Criminal Rules 5(f) and 10(c);

    e) A defendant who does not object to detention should, before the date of the detention hearing, notify the emergency judge orally through counsel or in writing that the defendant has no objection to detention. The absence of objection may be lodged without prejudice to re-raising pretrial release at a later date.

    f) All hearings on the revocation of supervised release scheduled to begin before April 3, 2020 are continued and will be rescheduled by the presiding judge to a date on or after April 6, 2020, unless the defendant, defense counsel, United States Probation Office or the United States Attorney's Office notifies the emergency judge that the hearing is necessary prior to April 6, 2020;

    g) All plea hearings and sentencing hearings scheduled to begin before April 3, 2020 are continued and will be rescheduled by the presiding judge to a date on or after April 6, 2020, unless the prosecutor or the defense notifies the emergency judge that the plea hearing or the

sentencing must be held before April 6, 2020.

h) In criminal cases, the court finds that the period of any continuance entered from the date of this order through April 6, 2020 as a result of this order shall be EXCLUDED under the Speedy Trial Act, 18 U.S.C. §3161(h)(7)(A), because the court finds that the ends of justice served by taking that action outweigh the interests of the parties and the public in a speedy trial, given the need to protect the health and safety of defendants, their counsel, prosecutors, court staff, and the public by reducing the number of in-person hearings to the greatest extent possible. The Court may extend the period of exclusion as circumstances may warrant.

i) All other criminal hearings of any kind scheduled from March 17, 2020 until April 3, 2020 are stricken from the calendar, to be re-set by the presiding judge for a date on or after April 6, 2020. Also, any other deadlines, including motions, briefing, and discovery deadlines, whether set by the court or by the Rules of Criminal Procedure or Local Rules, are hereby extended by 21 days from the current deadline set. This 21-day extension is subject to modification by the presiding judge assigned to the case.

j) The parties are cautioned that this Amended General Order does **not** affect the rights to or deadlines concerning any **appeal** from any decision of this Court. That is, the deadlines for filing a notice of appeal remain in place and must be followed to preserve appellate rights. Nonetheless, on its own motion and pursuant to Appellate Rule 4(b)(4), and in light of current public-health concerns, the Court (i) finds that good cause exists in every criminal case to extend the time to appeal for 30 days from the expiration of the time otherwise prescribed in Appellate Rule 4(b), and (ii) extends the appeal deadline in every criminal case by 30 days.

4. Any party may seek emergency relief from this General Order. In addition to filing the motion in the case in which the emergency relief is being sought, the party also must file the motion in Case No. 20-cv-01792, which is a docket created to receive emergency motions under this Amended General Order. The motion must be filed (i) electronically via CM/ECF if possible or (ii) via a paper-copy motion (following guidance in Paragraphs 5 and 6 of this Order) with the Clerk's Office. The motion will be considered by the presiding judge, an emergency judge, or the Chief Judge.

5. During the effective period of this Order, the District Court Clerk's Office in the Dirksen United States

Courthouse in Chicago, Illinois, will be open with limited staff. If possible, filings should be made electronically via CM/ECF. Deliveries of documents of any kind in the Eastern Division must be made to the drop boxes in the lobby of the Dirksen Courthouse or the Clerk's Office located on the 20th floor. No deliveries may be made to chambers.

6. During the effective period of this Order, the District Court Clerk's Office in the Stanley J. Roszkowski United States Courthouse in Rockford, Illinois, will be closed to the public. Filings in the Western Division can be: (i) electronically filed via CM/ECF; (ii) deposited in the drop box located on the 2nd floor of the Roszkowski United States Courthouse during business hours; (iii) mailed to US District Court Clerk's Office, 327 South Church Street, Rockford, IL 61101; or (iv) made in person in the Eastern Division at US District Court Clerk's Office, 219 South Dearborn Street, 20th Floor, Chicago, IL 60604 during business hours. No deliveries may be made to chambers.
7. During the effective period of this Amended General Order, all public gatherings are suspended at both the Everett McKinley Dirksen U.S. Courthouse in Chicago and the Stanley J. Roszkowski U.S. Courthouse in Rockford. This includes, but is not limited to, group tours and visits, moot courts and mock trials, bar group meetings, seminars, and naturalization ceremonies. Also suspended are Second Chance reentry court proceedings; SOAR Court; Veterans Treatment court proceedings, and Petty Offense (CVB) proceedings. The only exceptions are court proceedings that are allowed under some other provision of this Order.
8. The Court may issue other orders concerning future continuances as necessary and appropriate.
9. Electronic filings may still be made through the CM/ECF system.
10. This General Order does not affect the authority of judges to enter orders in any civil or criminal cases.
11. For emergency matters, as defined by Local Rule 77.2, that arise during business hours (Monday through Friday 7:00 a.m. through 6:00 p.m.), parties are directed to send an e-mail message to Emergency_Judge@ilnd.uscourts.gov. The Clerk will monitor the mailbox and send a response. If an emergency matter arises outside of regular business hours, arrangements to bring that matter before the emergency judge may be made by calling (312) 702-8875 and leaving a complete message, including a return telephone number. The Clerk will return the call.
12. The Court will vacate, amend, or extend this General Order no later than April 3, 2020.

13. The Clerk of Court shall distribute this Amended General Order by electronic service to all registered CM/ECF users; by first-class mail to unregistered litigants, including pro se litigants, and to attorneys pending pro hac vice admission; and by posting the General Order on the Court's public website.

ENTER:

FOR THE COURT

Chief Judge

Dated at Chicago, Illinois this 17th day of March, 2020

Exhibit 9

Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization

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Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to https://www.regulations.gov. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-2019-D-0661.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. ET.

Additional copies are available online at https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

January 2020

Table of Contents

Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization

Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document describes how we intend to prioritize our enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization.[2]

[1] This guidance was prepared by the Office of Compliance and Enforcement, Office of Health Communication and Education, Office of Regulations, and Office of Science in the Center for Tobacco Products at FDA.

[2] As with FDA's prior compliance policies on deemed new tobacco products that do not have premarket authorization, this guidance document does not apply to any deemed product that was not on the market on August 8, 2016.

For ENDS products marketed without FDA authorization, FDA intends to prioritize enforcement against:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.[3]

Further, FDA intends to prioritize enforcement of any ENDS product that is offered for sale after May 12, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

This guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization. FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, and it will continue to do so with respect to these products. FDA will take appropriate action regarding tobacco products that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors' use of those products.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Statutory and Regulatory History

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product[4] to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387 through 387u) (section 901(b) of the FD&C Act).

[3] For purposes of this Final Guidance, FDA's use of the term "minor" refers to individuals under the age of 21. This is consistent with the Further Consolidated Appropriations Act, 2020 (H.R. 1865), signed into law on December 20, 2019, which included a provision amending section 906(d) of the Federal Food, Drug, and Cosmetic Act to increase the federal minimum age to purchase tobacco products from 18 to 21, and adding a provision that it is unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age. In addition, FDA is working to update our regulations within 180 days, consistent with the timeline set forth in the law.

[4] 21 U.S.C 321(rr) (section 201(rr) of the FD&C Act).

In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of a tobacco product, except accessories of deemed tobacco products, to be subject to FDA's tobacco product authority. This included electronic nicotine delivery systems (ENDS), cigars, waterpipe (hookah) tobacco, pipe tobacco, nicotine gels, and dissolvables that were not already subject to the FD&C Act (81 FR 28974 at 28976 (May 10, 2016)).

The requirements in Chapter IX of the FD&C Act now apply to deemed products. Particularly relevant to this guidance is section 910, which imposes certain premarket-review requirements for "new tobacco products"—*i.e.*, those that were not commercially marketed in the United States as of February 15, 2007. Accordingly, after the rule's effective date, deemed new tobacco products were required to obtain premarket authorization under Section 910. Deemed new tobacco products that remain on the market without marketing authorization are marketed unlawfully in contravention of the Tobacco Control Act. Through the premarket review process, FDA conducts a science-based evaluation to determine whether a new tobacco product meets the applicable statutory standard for marketing authorization—for example, whether the product is appropriate for the protection of public health with respect to the risks and benefits to the population as a whole, including users and nonusers, and taking into account, among other things, the likelihood that those who do not use tobacco products will start using them.

The preamble to the May 10, 2016, final deeming rule explained that FDA intended to defer enforcement for failure to have premarket authorization during two compliance periods related to premarket review: one for submission and FDA receipt of applications and one for obtaining premarket authorization. The first compliance period depended on the type of application. The compliance date was 12 months from the effective date of the rule for substantial equivalence exemption requests (EX REQs), 18 months for substantial equivalence reports (SE Reports), and 24 months for premarket tobacco applications (PMTAs). In addition, the preamble explained that under the second compliance period:

> Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period.[5]

The preamble further explained that this compliance policy did not apply to any new tobacco product that was not on the market on August 8, 2016. Significantly, this policy did not confer lawful marketing status on new tobacco products being marketed without the necessary premarket authorization.

In May 2017, FDA published a guidance document, *Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule*, under which the Agency, as

[5] 81 FR at 29011.

a matter of enforcement discretion, stated its intention to defer enforcement for an additional three months for all future compliance dates for requirements under the final deeming rule.

In July 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation that would serve as a multi-year roadmap in an effort to significantly reduce tobacco-related disease and death. Prior to this announcement, nationally representative data suggested that youth use of e-cigarettes had declined beginning in 2016.[6] The comprehensive plan was announced in part to afford the Agency time to explore clear and meaningful measures to make combustible tobacco products less toxic, less appealing, and less addictive. One aspect of the plan involved striking a balance between regulation and encouraging development of innovative tobacco products that may be less harmful than cigarettes. The Agency announced that it planned to issue an updated compliance policy further deferring some enforcement timelines described in the final deeming rule.

In accordance with this comprehensive plan, in August 2017, FDA announced an extension of the period during which it did not intend to initiate enforcement action for premarket review requirements under the final deeming rule ("August 2017 Compliance Policy") for deemed tobacco products that were on the market on August 8, 2016. This revised policy stated that, for these products, FDA did not intend to initiate enforcement regarding submitting EX REQs, SE Reports, and PMTAs for newly regulated combusted tobacco products (such as most cigars) until August 8, 2021, and FDA did not intend to initiate enforcement regarding EX REQs, SE Reports, and PMTAs for newly regulated noncombusted tobacco products (such as most ENDS products) until August 8, 2022. In addition, FDA revised the compliance policy relating to the period after FDA receipt of EX REQs, SE Reports, and PMTAs for deemed tobacco products that were on the market on August 8, 2016. FDA stated that, under this policy, it intended to continue deferring enforcement until the Agency rendered a decision on an application (*i.e.*, issuance of: a Marketing Order; a No Marketing Order; a Refuse to File; or a Refuse to Accept) or the application was withdrawn.

In March 2018, the August 2017 Compliance Policy was challenged in the U.S. District Court for the District of Maryland, and on May 15, 2019, the court issued an order that vacated the guidance.[7] On July 12, 2019, the court issued a further order directing FDA to require that premarket authorization applications for all new—*i.e.*, not "grandfathered"[8]—deemed tobacco products be submitted to the Agency within 10 months, by May 12, 2020, and providing for a one-year period during which products with timely filed applications might remain on the market

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[6] Jamal, A., A. Gentzke, S.S. Hu, et al., "Tobacco Use Among Middle and High School Students — United States, 2011–2016," Morbidity and Mortality Weekly Report, 66:597–603, 2017, available at: https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm.

[7] *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, 379 F. Supp. 3d 461, 496 (D. Md. 2019).

[8] A "grandfathered" product is one that was on the market as of February 15, 2007. Guidance, Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007, dated September 2014, available at: https://www.fda.gov/media/123544/download.

pending FDA review.[9] As required by the court's order, deemed new tobacco products on the market as of August 8, 2016, for which premarket authorization applications are not filed by May 12, 2020, are subject to FDA enforcement actions, in the Agency's discretion.[10] The court subsequently clarified that its order did not restrict FDA's authority to enforce the premarket review provisions against deemed products, or categories of deemed products, prior to May 12, 2020, or during the one-year review period.[11]

B. FDA Response to Evidence of Increasing Youth Use of ENDS Products

In late 2017, FDA started to see a marked increase in complaints about ENDS products. FDA initiated an investigation of these complaints, the majority of which pertained to minors' access to and use of these products. This new information indicated an alarming increase in the use of ENDS products by middle and high school students. In April 2018, FDA conducted a nationwide undercover enforcement effort that resulted in FDA issuing 56 warning letters to online retailers and 6 civil money penalty (CMP) complaints to retail establishments related to the illegal sales of certain ENDS products to minors. In addition, FDA sent an official request for information to manufacturers of certain ENDS products commonly used by minors requiring them to submit documents to facilitate the Agency's understanding of the reported high rates of youth use and the particular youth appeal of these products. FDA also took measures to address the sale of ENDS products to minors online by contacting eBay to raise concerns over several listings on its website. This resulted in listings for these ENDS products being removed from eBay.

In May 2018, FDA issued 17 warning letters to manufacturers, distributors, and retailers for selling e-liquids with labeling and/or advertising that resemble kid-friendly food products, such as juice boxes, candy, or cookies. The warning letters stated that failure to correct violations may result in FDA initiating further action such as seizure or injunctive relief. Of these warning letters, 13 were issued as part of a joint action with the Federal Trade Commission (FTC).

On September 12, 2018, FDA announced a series of enforcement and other regulatory actions related to the labeling and advertising of ENDS products, including that it had conducted nationwide, undercover investigations of brick-and-mortar and online stores over the summer of 2018 and issued more than 1,300 warning letters and CMP complaints to retailers who illegally sold ENDS products to minors. FDA also issued 12 warning letters to online retailers that were selling misleadingly labeled and/or advertised e-liquids resembling kid-friendly food products such as candy and cookies.

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[9] *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), 2019 WL 3067492, at *7 (D. Md. July 12, 2019) (Dkt. No. 127). The court has granted intervention to vapor industry trade associations for purposes of appealing the court's decision and remedies order. *See American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), Dkt. No. 154 (Oct. 2, 2019). An appeal is pending. *See American Academy of Pediatrics v. Cigar Ass'n of America*, Nos. 19-2130, -2132, -2198, -2242 (4th Cir.).

[10] *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), 2019 WL 3067492, at *7 (D. Md. July 12, 2019) (Dkt. No. 127).

[11] *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, Case No. 8:18-cv-883 (PWG), (D. Md. Aug. 12, 2019), Dkt. No. 132.

In addition, on September 12, 2018, FDA issued letters to five ENDS product manufacturers, requesting each company to submit a plan describing how it would address minors' access to and use of its products.

In response to the September 12th letters to industry, manufacturers described safeguards that they could implement to help to restrict minors' access to ENDS products sold at brick and mortar retailers and online. Examples of potential safeguards included:

- Establishing or enhancing programs, such as mystery shopper programs, to monitor retailer compliance with age-verification and sales restrictions;
- Establishing and enforcing contractual penalties for contracted retailers that sell tobacco products to youth;
- Using age-verification technology to better restrict access to the manufacturer's website, such as through independent, third-party age- and identity-verification services that compare customer information against third-party data sources; and
- Limiting the quantity of ENDS products that a customer may purchase within a given period of time.

In conjunction with issuing the September 2018 letters, FDA announced in September 2018 that the Agency was considering whether, in light of current information, it would be appropriate to revisit the August 2017 Compliance Policy, which could result in withdrawing or revising the policy with respect to certain flavored products that may be contributing to the rise in youth use and having firms "remove some or all of [these] products . . . until they receive premarket authorization and otherwise meet all of their obligations under the law."[12] Following the September 12th letters and announcement, FDA repeatedly publicly discussed[13] the fact that these compliance timelines were under reconsideration and solicited the view of stakeholders—including manufacturers, retail associations, and public interest organizations.[14]

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[12] FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access (Sept. 11, 2018), available at: https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more.

[13] *See*, *e.g.,* Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes, available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm; Scudder, L., "Vaping and E-Cigarettes in Kids: An Unprecedented Epidemic," Medscape, January 28, 2019, available at: https://www.medscape.com/viewarticle/908077?faf=1.

[14] *See, e.g.,* FDA Public Calendar – Meeting With FDA Officials, available at: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-calendar-meetings-fda-officials (noting meetings held on October 11, 16, 18, 29 and 30 of 2018; November 13, 2018; and December 19, 2018); February 6, 2019 Letters sent to JUUL Labs, Inc. and Altria Group Inc., requesting meetings to discuss concerns related youth addiction to tobacco products, available at: https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/ctp-letters-industry.

Since the effective date of the Deeming Rule in August 2016, FDA has issued more than 10,000 warning letters and more than 1,400 CMP complaints to retailers for the sale of ENDS products to minors. Specifically, from April 2018 through August 2019, FDA issued over 6,000 warning letters and more than 1,000 CMP complaints to retailers for the sale of ENDS products to minors. Since May 2018, FDA has also issued over 40 warning letters to manufacturers, distributors, and retailers for selling e-liquids with false or misleading labeling and/or advertising that resemble kid-friendly products. In June 2019, the Agency issued joint FDA/FTC warning letters to four e-liquid manufacturers for violations related to online posts by social media influencers on the companies' behalf. In September 2019, FDA issued a warning letter to an ENDS manufacturer for marketing unauthorized modified risk tobacco products, including in outreach to youth.[15] FDA will continue to use all available tools to prevent youth use of all tobacco products, including ENDS products.

In 2018, FDA continued to receive information underscoring the problem of youth use of ENDS products. Current e-cigarette use had increased considerably among U.S. middle and high school students during 2017–2018, reversing a decline in e-cigarette use that had been observed in recent years and increasing overall tobacco product use in 2018. Specifically, among high school students, current e-cigarette use had increased by 78 percent in the past year (from 11.7 percent in 2017 to 20.8 percent in 2018, $p<0.001$), while among middle school students, current e-cigarette use had increased by 48 percent (from 3.3 percent in 2017 to 4.9 percent in 2018, $p = 0.001$).[16] Frequent use among high school students (defined as use on ≥ 20 of the past 30 days) also had increased, from 20.0 percent in 2017 to 27.7 percent in 2018 ($p = 0.008$).[17] Data from this study, as well as the concerns described above, prompted FDA to issue a draft guidance, "Modifications to Compliance Policy for Certain Deemed Tobacco Products" ("March 2019 Draft Guidance"), regarding the continued marketing of deemed tobacco products that have not obtained premarket authorization, and to call on industry to do more to keep their products out of the hands of minors.

In 2019, two of the largest surveys of tobacco use among youth found that e-cigarette use has hit the highest levels ever recorded. As detailed in Section IV below, data from both the National Youth Tobacco Survey (NYTS) and the Monitoring the Future (MTF) Study have documented a continued increase in youth use of ENDS products and further underscored the magnitude of the problem. These data, information conveyed to FDA in comments to the March 2019 Draft Guidance, and concern about health and safety issues connected to these products—*e.g.*, the harmful effects of nicotine on adolescent brain development, as well as battery explosions with ENDS products—continue to inform FDA's serious public health concerns regarding the sale of these products without premarket authorization. Repeated exposure to nicotine during

[15] For more information, please see https://www.fda.gov/news-events/press-announcements/fda-warns-juul-labs-marketing-unauthorized-modified-risk-tobacco-products-including-outreach-youth.

[16] Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018," Morbidity and Mortality Weekly Report, 67(45);1276-1277, 2018.

[17] *Id.*

adolescence induces long-lasting changes in brain regions involved in addiction, attention, learning, and memory.

Furthermore, as of December 17, 2019, there have been approximately 2,506 reported cases of hospitalizations for lung injuries associated with use of vaping products ("hospitalized EVALI patients"), including 54 confirmed deaths.[18] Working closely with other federal and state agencies, FDA has not been able to determine the cause of this outbreak. It appears that most of the patients impacted by these illnesses reported using THC-containing products, with evidence suggesting that additive agents, specifically Vitamin E, may play a causative role. In many of the cases, individuals reported using multiple products, including some with nicotine. Many different substances and product sources are still under investigation.

Although this guidance does not address products that are not tobacco products, the outbreak of lung injuries associated with use of vaping products illustrates public health and safety concerns that may arise for products for which information related to product safety and health impact are lacking and affirms the importance of the premarket review process, as contemplated by the Tobacco Control Act, to scientifically evaluate products based on a public health standard.

Accordingly, FDA is issuing this Final Guidance to communicate its enforcement priorities with respect to ENDS products. FDA's decision to exercise its enforcement authorities with respect to particular products will be determined on a case-by-case basis, informed by the enforcement priorities described in this Final Guidance and any other relevant factors.[19]

III. DEFINITIONS

For purposes of this guidance, FDA intends to use the following definitions:

Cartridge-based ENDS products are a type of ENDS product that consists of, includes, or involves a cartridge or pod that holds liquid that is to be aerosolized through product use. For purposes of this definition, a cartridge or pod is any small, enclosed unit (sealed or unsealed) designed to fit within or operate as part of an electronic nicotine delivery system.[20]

Electronic nicotine delivery systems (or ENDS) include devices, components, and/or parts that deliver aerosolized e-liquid when inhaled. For example, FDA considers vapes or vape pens, personal vaporizers, e-cigarettes, cigalikes, e-pens, e-hookahs, e-cigars, and e-pipes to be ENDS.

E-liquids are a type of ENDS product and generally refer to liquid nicotine and nicotine-containing e-liquids (*i.e.*, liquid nicotine combined with colorings, flavorings, and/or other

[18] *See* Centers for Disease Control and Prevention, "Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping," available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information.

[19] *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (providing that the FD&C Act's enforcement provisions commit broad discretion to the Secretary to decide how and when they should be exercised).

[20] An example of products that would not be captured by this definition include completely self-contained, disposable products.

ingredients). Liquids that do not contain nicotine or other material made or derived from tobacco, but that are intended or reasonably expected to be used with or for the human consumption of a tobacco product, may be components or parts and, therefore, subject to FDA's tobacco control authorities.

Label means a display of written, printed, or graphic matter upon the immediate container of any article. Section 201(k) of the FD&C Act.

Labeling means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. Section 201(m) of the FD&C Act.

New tobacco product means (1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. Section 910(a) of the FD&C Act.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that under the FD&C Act is a drug (section 201(g)(1) (21 U.S.C 321(g)(1))), a device (section 201(h)), or a combination product (section 503(g) (21 U.S.C 353(g))). Section 201(rr) of the FD&C Act.

IV. ENFORCEMENT PRIORITIES REGARDING CERTAIN ENDS PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION

A. Overview

The Tobacco Control Act provides that new tobacco products (*i.e.*, non-grandfathered products) may not legally be marketed without premarket authorization. Accordingly, all deemed new tobacco products on the market without authorization are illegally marketed products.

Beginning 30 days after issuance of this Final Guidance, FDA intends to prioritize enforcement of the premarket review requirements for certain ENDS products, including against retailers selling such products. Specifically, FDA intends to prioritize enforcement against:

(1) Flavored, cartridge-based ENDS products (except for tobacco- or menthol-flavored products);
(2) All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
(3) Any ENDS products targeted to, or whose marketing is likely to promote use by, minors.

In addition, FDA intends to prioritize enforcement of any ENDS product that is offered for sale in the United States after May 12, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).[21]

FDA will make enforcement decisions on a case-by-case basis, recognizing that it is unable, as a practical matter, to take enforcement action against every illegally marketed tobacco product, and that it needs to make the best use of Agency resources. This guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization, or to sell any tobacco product to minors. The Agency also retains discretion to pursue enforcement action at any time against any deemed new tobacco product marketed without premarket authorization, regardless of whether it falls within one of these categories of enforcement priorities.

B. Data Show Substantial Increase in Youth Use of ENDS Products, Particularly Certain Flavored, Cartridge-Based ENDS Products

At the time FDA issued the August 2017 Compliance Policy to announce changes in its approach to enforcement regarding premarket authorization (as described in the preamble to the final deeming rule), data from the 2016 NYTS showed a decrease in prevalence of current e-cigarette use (*i.e.*, past 30-day use) among high school students, from 16 percent in 2015 to 11.3 percent in 2016.[22] Results from the 2017 NYTS later confirmed that in regards to youth use there was no statistically significant rise at the time, with data suggesting that high school student use had leveled off between 2016 (11.3 percent)[23] and 2017 (11.7 percent).[24]

However, multiple survey results over the past several years demonstrate that there is significant initiation by youth. The recent surge in youth use of ENDS products has caused us to reevaluate our July 2017 assessment and to modify our enforcement priorities for ENDS products. Recent data show an alarming increase in youth use of ENDS products in the past two years. They also show youth are more likely to use certain flavored, cartridge-based ENDS products.

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[21] We note that FDA would be enforcing the priorities discussed in Section IV of this guidance regardless of the court's decision in the *AAP* case. As discussed in this Final Guidance, FDA is implementing this policy to address the alarming increase in youth use of ENDS products as well as other recent health and safety issues regarding such products.

[22] Jamal, A., A. Gentzke, S.S. Hu, et al., "Tobacco Use Among Middle and High School Students — United States, 2011–2016," Morbidity and Mortality Weekly Report, 66:597–603, 2017, available at: https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm.

[23] *Id*.

[24] Wang, T.W., A. Gentzke, S. Sharapova, et al., "Tobacco Product Use Among Middle and High School Students – United States, 2011-2017," Morbidity and Mortality Weekly Report, 67:629-633, 2018, available at: http://dx.doi.org/10.15585/mmwr.mm6722a3.

Overall, data showed that ENDS product use more than doubled among middle school and high school students from 2017 to 2019.[25] Data from MTF showed that from 2017 to 2018, current (past 30-day) e-cigarette use significantly increased from 6.6 percent to 10.4 percent among 8th graders (a 58 percent increase), 13.1 percent to 21.7 percent among 10th graders (a 66 percent increase), and 16.6 percent to 26.7 percent among 12th graders (a 61 percent increase).[26] This trend continued in the 2019 MTF data. The number of students who had used ENDS products during the previous 12 months and those who had ever used ENDS products significantly increased in 8th, 10th, and 12th grade from 2018 to 2019.[27] Data from the NYTS for the same time period show that, between 2017 and 2018, current e-cigarette use among high school students increased from 11.7 percent to 20.8 percent (a 78 percent increase, $p<0.001$).[28] Current e-cigarette use among middle school students also increased from 3.3 percent to 4.9 percent over the same time period (a 48 percent increase, $p=0.001$), which we calculated as an increase of an estimated 180,000 middle school students reporting past 30-day e-cigarette use in one year.[29] The data from 2019 NYTS have also documented that this is the second year in a row where current (past 30-day) e-cigarette use reached new highs among youth.[30] The prevalence of current e-cigarette use among high school students was 27.5 percent and middle school students was 10.5 percent.[31] Among high school students, 4.11 million reported having used an e-cigarette in the past month in 2019 with 1.24 million middle school students reporting the same. For the first time ever, the total number of middle and high school students reporting current use of e-cigarettes surpassed 5 million in 2019.[32]

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[25] Miech R, L. Johnston, P.M. O'Malley, et al., "Trends in adolescent vaping, 2017–2019," New England Journal of Medicine, 381:1490-1491, 2019; DOI:10.1056/NEJMc1910739.

[26] Miech, R. A., Johnston, L. D., O'Malley, P. M., et al., "Monitoring the Future national survey results on drug use, 1975–2018: Volume I, Secondary school students," Ann Arbor: Institute for Social Research, The University of Michigan (2019), available at http://monitoringthefuture.org/pubs.html#monographs. For each age group, the increase from 2017 to 2018 was statistically significant ($p<.001$).

[27] Miech R, L. Johnston, P.M. O'Malley, et al., "Trends in adolescent vaping, 2017–2019," New England Journal of Medicine; 381:1490-1491, 2019; DOI:10.1056/NEJMc1910739.

[28] Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018," Morbidity and Mortality Weekly Report, 67(45);1276-1277, 2018. The NYTS defines e-cigarettes as "battery-powered devices that provide nicotine and other additives to the user in the form of an aerosol."

[29] *Id.*

[30] Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21);2095-2103, 2019. Several improvements were made to the NYTS in 2019, including switching from paper-and-pencil to electronic survey administration, adding skip patterns and example product images, and updating brand examples to reflect the current tobacco marketplace (*e.g.*, adding JUUL), which may affect the comparability of tobacco product use behaviors, including e-cigarette use behaviors, with previous years. Although trend analyses, which use more data points and are not solely dependent on changes during a single year, may be conducted without major shifts in patterns or findings, the exact magnitude of the effect of these survey improvements in 2019 cannot be fully quantified. Thus, direct statistical comparisons between estimates of tobacco product use between 2018 and 2019 were not conducted.

[31] Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21);2095-2103, 2019.

[32] *Id.*

Disturbingly, these data also indicate that a growing percentage of America's youth who use e-cigarettes have become frequent e-cigarette users (defined as reporting use on 20 days or more of the prior 30-day period). An increasing number of youth are thus at greater risk of nicotine addiction at a time when the developing brain is particularly susceptible to permanent changes from nicotine use and when almost all nicotine addiction is established.[33] Data from the 2019 NYTS have documented continued frequent youth ENDS use.[34] The proportion of current high school e-cigarette users who reported use on 20 days or more (of the prior 30-day period), and thus were frequent users, was 34.2 percent in 2019.[35] The proportion of current middle school e-cigarette users who reported use on 20 days or more (of the prior 30-day period) was 18.0 percent in 2019.

This builds upon an increase in frequent ENDS use among youth who report using ENDS products observed in 2018. For example, data from the 2018 NYTS showed that the proportion of current high school e-cigarette users who reported use on 20 days or more (of the prior 30-day period) increased by 38.5 percent, from 20.0 percent in 2017 to 27.7 percent in 2018.[36] In a study that collected data from February to May 2018 and focused specifically on 15-to-17-year-old current users of JUUL products (the most commonly used brand, including among youth), 55.8 percent reported using such ENDS products on 3 or more of the previous 30 days, and over a quarter (25.3 percent) reported use on 10 to 30 days of the prior month.[37]

The concerns caused by the sharp increase in the number of youth using ENDS products are compounded by evidence indicating that youth whose first tobacco product is an ENDS product are at an increased risk of becoming cigarette smokers as compared to non-ENDS users. A 2018 report by the National Academy of Sciences, Engineering, and Medicine entitled "Public Health Consequences of E-Cigarettes," which took into account multiple lines of evidence across different studies and study designs, concluded that "there is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults."[38]

FDA is also concerned about the extraordinary popularity of flavored ENDS products with youth. Research has long shown that flavors increase youth appeal of tobacco products,

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[33] Miech R., Johnston L, O'Malley PM, et al., "Adolescent vaping and nicotine use in 2017–2018 — U.S. National Estimates," New England Journal of Medicine; 380:192-3, 2019.

[34] Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21);2095-2103, 2019.

[35] *Id*.

[36] Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018," Morbidity and Mortality Weekly Report, 67(45);1276-1277, 2018.

[37] Vallone, D.M., M. Bennett, H. Xiao, et al., "Prevalence and correlates of JUUL use among a national sample of youth and young adults," Tobacco Control,0:1-7, 2017, doi: 10.1136/tobaccocontrol-2018-05463.

[38] National Academies of Sciences, Engineering, and Medicine, "Public health consequences of e-cigarette,". Washington, DC: The National Academies Press, 2018, doi: https://doi.org/10.17226/24952.

including ENDS.[39] Evidence continues to accumulate, further confirming that youth are particularly attracted to flavored ENDS products. Data from the 2018 NYTS showed that past 30-day use of any flavored e-cigarette increased from 2017 among high school students who reported current e-cigarette use (60.9 percent to 67.8 percent, $p<0.05$).[40] In the 2016-2017 (Wave 4)[41] Population Assessment of Tobacco and Health (PATH) Study,[42] among youth age 12 to 17 who reported using an ENDS product, 93.2 percent reported that their first ENDS use was with a flavored ENDS product.[43] Data from Wave 4 also showed that 71 percent of current youth ENDS users said they used ENDS products "because they come in flavors I like."[44]

The NYTS survey instrument groups mint- and menthol-flavored products together, so it is not possible to differentiate youth use of mint and menthol flavors separately based on the NYTS data. The 2018 NYTS data indicate that, among high school students whose only tobacco product use is e-cigarettes, known as exclusive e-cigarette users, the proportion who reported fruit-flavored ENDS use was 75.5 percent in 2018[45] and the proportion who reported mint-and menthol-flavored ENDS use was 38.1 percent.[46] In 2019, in the same population, fruit-flavored ENDS use was 66.1 percent and mint- and menthol-flavored ENDS use was 57.3 percent.[47] Among middle school exclusive e-cigarette users, the 2018 NYTS data indicate that use of fruit-flavored ENDS use was 58.1 percent and mint-and menthol-flavored ENDS use was 20.6

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[39] *E.g.,* Carpenter, C.M., et al., "New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies," Health Affairs, 24(6):1601-1610, 2005; Pepper, J. K., K.M. Ribisl, N.T. Brewer, "Adolescents' interest in trying flavoured ecigarettes," Tobacco Control, 25:ii62-ii66, 2016; Camenga, D. R., M. Morean, G. Kong, et al., "Appeal and use of customizable e-cigarette product features in adolescents," Tobacco Regulatory Science, 4(2):51-60, 2018; Harrell, M.B., S.R. Weaver, A. Loukas, et al., "Flavored e-cigarette use: characterizing youth, young adult, and adult users," Preventive Medicine Reports, 5:33-40, 2017.

[40] Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018," Morbidity and Mortality Weekly Report, 67(45);1276-1277, 2018.

[41] Population Assessment of Tobacco and Health (PATH) Study [United States] Restricted Use Files (ICPSR 36231), available at: https://www.icpsr.umich.edu/icpsrweb/NAHDAP/studies/36231.

[42] The PATH study is a research study that assesses within-person changes and between-person differences in a large national cohort of participants aged 12 years and older over time. Each wave is a follow-up where the PATH study can examine its objectives, iteratively and cumulatively, to generate a broad body of knowledge about tobacco product use in the USA. Data collection for each wave occurred during the following timeframes: Wave 1 (September 2013-December 2014), Wave 2 (October 2014-2015), Wave 3 (October 2015-2016), and Wave 4 (2016-2017).

[43] Rostron B et al. "Prevalence and Reasons for Use of Flavored Cigars and ENDS among US Youth and Adults: Estimates from Wave 4 of the PATH Study, 2016-2017," American Journal of Health Behavior, 44(1);76-81, 2020.

[44] *Id.*

[45] Cullen, K.A., A.S. Gentzke, M.D. Sawdey, et al., "E-cigarette use among youth in the United States, 2019," JAMA, 322(21);2095-2103, 2019.

[46] Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018," Morbidity and Mortality Weekly Report, 67(45);1276-1277, 2018.

[47] Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21);2095-2103, 2019.

percent.[48] In 2019, in the same population, fruit-flavored ENDS use was 67.7 percent and mint- and menthol-flavored ENDS use was 31.1 percent.[49] Between 2016 and 2019, high school exclusive e-cigarette users who reported mint- and menthol-flavored ENDS use increased from 16.0 percent to 57.3 percent, $p<0.05$.[50] Data for middle school e-cigarette users was inconclusive on this point due to a limited number of middle-school students in the NYTS sample who not only used e-cigarettes within the past 30 days, but whose exclusive tobacco product use in the past 30 days was e-cigarettes.[51] In 2019, the data indicate that more than one million middle and high school exclusive e-cigarette users used mint- or menthol-flavored ENDS in the past 30 days.[52]

However, data from the MTF survey examine mint and menthol JUUL use separately and indicate that youth use of menthol-flavored products is not as high as that for mint- and fruit-flavored products. Specifically, a randomly-selected third of 2019 MTF respondents were asked about their flavored JUUL use.[53] The analytic sample included past 30-day JUUL users who answered the question, "Which JUUL flavor do you use most often?" with response options of Classic Tobacco, Crème, Cucumber, Fruit, Mango, Menthol, Mint, Virginia Tobacco, and Other. Among past 30-day JUUL users in each grade studied (8th, 10th, and 12th), use of mango and mint ranked highest, followed by fruit. Reported use of menthol and tobacco flavors were among the lowest ranked options. Specifically, a number of 8th grade past 30-day JUUL users reported use of mango (33.5 percent), while the others reported use of mint (29.3 percent), fruit (16.0 percent), and other (14.8 percent).[54] A large percentage of 10th grade past 30-day JUUL users reported use of mint (43.5 percent), while the others reported use of mango (27.3 percent), fruit (10.8 percent), and other (8.4 percent).[55] Close to half of 12th grade past 30-day JUUL users reported use of mint (47.1 percent), while the others reported use of mango (23.8 percent), fruit (8.6 percent), other (6.0 percent), menthol (5.9 percent), and cucumber (4.4 percent).[56]

Data from the 2019 NYTS also indicate that youth overwhelmingly prefer cartridge-based ENDS products,[57] and we have found that these products are easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale. The 2019 survey instrument included a measure for the "usual brand" of e-cigarette used in the past 30 days.

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[48] *Id*.

[49] *Id*.

[50] *Id*.

[51] *Id*.

[52] *Id*.

[53] Leventhal A., et al., "Flavors of e-Cigarettes Used by Youths in the United States," JAMA, 322(21):2132-2134, 2019.

[54] The remaining flavors, including tobacco and menthol flavors, each had estimates of ≤ 2.3%.

[55] The remaining flavors, including tobacco and menthol flavors, each had estimates of ≤ 3.0%.

[56] The remaining flavors, including tobacco flavors, each had estimates of ≤ 1.5%.

[57] Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21);2095-2103, 2019.

Most youth who were current e-cigarette users reported a cartridge-based e-cigarette as their usual brand.[58] In fact, the leading brand is a cartridge-based product that commands approximately 70 percent of the market.[59]

Of particular concern are the design features that appear to make the cartridge-based products so popular with young people. Attributes typically present in cartridge-based products include a relatively small size that allows for easy concealability, and intuitive and convenient features that facilitate ease of use, including draw activation, prefilled cartridges or pods, and USB rechargeability.

Small products may allow youth to use the product in circumstances where use of tobacco products is prohibited, such as a school.[60] Small size may also allow the user to quickly conceal the product in the palm of one's hand or in a pocket.[61] Small size may allow for product use in a social setting without others' awareness,[62] particularly in conjunction with vaping techniques that may be used to prevent or hide the vapor cloud. Additionally, depending on the size and shape of the product, it may also blend in with other equipment that is expected in that setting (*e.g.*, if the ENDS is shaped like a flash drive, for example, next to a computer, where an actual flash drive would be used), or it may otherwise go undetected because parents, teachers, or coaches do not recognize the product as an ENDS.[63]

Products ready for use immediately after purchase have characteristics that facilitate ease of use among young people. With cartridge-based products, there are no settings to change and very little assembly is required. Research on other tobacco products suggests that ease of use is associated with susceptibility to tobacco product uptake among youth.[64] Additional research among youth suggests that younger adolescents are more likely to use more basic ENDS

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[58] *Id*. Unpublished data from the 2019 survey list other brands that are used by youth, some of which are available in both cartridge-based and non-cartridge-based forms.

[59] Nielsen Total US xAOC/Convenience Database & Wells Fargo Securities, LLC, in Wells Fargo Securities, Nielsen: Tobacco All Channel Data Thru 10/4 – Cig Vol Declines Moderate, October 15, 2019.

[60] See, e.g., Schillo B., et al., "JUUL in School: Teacher and Administrator Awareness and Policies of E-Cigarettes and JUUL in U.S. Middle and High Schools," Health Promot Pract., 21(1):20-24, 2020; "Why 'juuling' has become a nightmare for school administrators," Kaiser Health News (March 26, 2018), available at: https://www.nbcnews.com/health/kids-health/why-juuling-has-become-nightmare-school-administrators-n860106/; "Juul Is Sued by School Districts That Say Vaping Is a Dangerous Drain on Their Resources," The New York Times (October 7, 2019), available at: https://www.nytimes.com/2019/10/07/us/juul-vaping-schools.html.

[61] http://pittsburgh.cbslocal.com/2017/12/13/new-ecigarette-popular-among-kids-easy-to-conceal-from-parents/

[62] https://www.npr.org/sections/health-shots/2017/12/04/568273801/teenagers-embrace-juul-saying-its-discreet-enough-to-vape-in-class

[63] https://www.excelsiorspringsstandard.com/news/new-vaping-devices-may-go-undetected-by-parents/

[64] Chaffee B.W., J. Urata, E.T. Couch, S. Gansky, "Perceived flavored smokeless tobacco ease-of-use and youth susceptibility," Tobacco Regulatory Science, 3(3):367-373, 2017.

products than older adolescents.[65] Thus, particularly easy-to-use products, such as cartridge-based products, may have lower barriers to initiation.

Other product features that facilitate ease of use include pre-filled cartridges, which are convenient because they do not require filling prior to use and are easy to dispose of and replace; a draw-activated battery that makes the devices much easier to use than other devices; and rechargeability, an important characteristic for use among youth who recharge via a USB port when connected to a computer or charging adapter from other electronic devices, such as a cellphone.

In the notice of proposed rulemaking for the Deeming Rule, FDA noted that the overall public-health impact of ENDS products would depend crucially upon "who uses the products and how they are used. If such products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is a potential for the net public health impact at the population level to be positive. If, on the other hand, there is significant initiation by youth, minimal quitting, or significant dual use of combust[ed] and non-combust[ed] products, then the public health impact could be negative."[66] The data discussed above demonstrate substantial and increasing initiation of ENDS products by youth, particularly certain flavored, cartridge-based products.

C. Additional Relevant Considerations

In issuing the March 2019 Draft Guidance, FDA solicited public comment generally on the proposed approach and specifically sought information that could help inform its decision-making for each key issue. In developing this Final Guidance, FDA considered information provided in the public comments submitted on the March 2019 Draft Guidance. Overall, out of the over 15,000 public comments FDA received in response to the Draft Guidance, many were related to form letter campaigns, while approximately 294 public comments provided unique and substantive information. In addition to the comments that provided unique and substantive information, FDA received thousands of general comments expressing support or opposition to the guidance and separate provisions within the guidance. These comments express broad policy views and do not address specific points related to the March 2019 Draft Guidance. Additional information regarding significant comments received in response to the March 2019 Draft Guidance and FDA's responses is described in Appendix A.[67]

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[65] Pepper J.K., A.J. MacMonegle, J.M. Nonnemaker, "Adolescents' use of basic, intermediate, and advanced device types for vaping," Nicotine & Tobacco Research, 21(1):55–62, 2019.

[66] 79 Fed. Reg. 23141, 23147 (2016).

[67] FDA generally does not respond to comments in guidance documents and, as noted in the preamble to the deeming rule, generally "[a]gency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking." 81 Fed. Reg. at 28,977, 29,010 (citing *Prof'ls & Patients for Customized Care v. Shalala*, 56 F.3d 592 (5th Cir. 1995) (a compliance policy guide is not a substantive rule and not subject to APA's notice-and-comment rulemaking); *Takhar v. Kessler*, 76 F.3d 995, 1002 (9th Cir. 1996) (FDA compliance policy guides were not required to go through notice-and-comment procedures)). Although FDA is addressing comments here, it does so voluntarily and given the circumstances. By responding to comments here, FDA in no way

FDA also remains concerned about health and safety issues connected to ENDS products—*e.g.*, cases of lung injuries associated with use of vaping products[68] as well as battery explosions with ENDS products[69]—particularly given that these products have been marketed without premarket evaluation. These current public health issues affirm the importance of the premarket review process, as contemplated by the Tobacco Control Act, to scientifically evaluate products based on a public health standard. For example, FDA review of premarket tobacco product applications considers the risks and benefits of the product to the population as a whole, including tobacco product users and non-users. In reviewing premarket tobacco product applications, FDA will consider, among other things: the product's components, ingredients, additives, and properties; manufacturing practices; and any studies or investigations into the health risks of the tobacco product.

D. Enforcement Priorities for ENDS Products

In the discussion that follows, we describe our current intent regarding prioritizing our enforcement resources with respect to certain illegally marketed ENDS products.

FDA will prioritize enforcement of flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored products), which are produced primarily by large manufacturers. This policy should have minimal impact on small manufacturers (*e.g.*, vape shops) that primarily sell non-cartridge-based ENDS products, unless they market to youth or fail to take adequate measures to prevent youth access. Specifically, FDA intends to prioritize enforcement regarding the lack of marketing authorization against:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.

FDA intends to prioritize enforcement beginning 30 days after issuance of this Final Guidance.

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establishes a policy, practice, or precedent requiring the Agency to do so with respect to future iterations of this document or any other guidance document.

[68] *See, e.g.*, Centers for Disease Control and Prevention, "Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping," available at: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information; Layden, J. E., I. Ghinai, I. Pray, et al., "Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin – Preliminary Report," New England Journal of Medicine, Sept. 2019; DOI: 10.1056/NEJMoa1911614.

[69] *See, e.g.*, Rossheim, M.E., M.D. Livingston, E.K. Soule, et al., "Electronic Cigarette Explosion and Burn Injuries, US Emergency Departments 2015-2017," Tobacco Control, 2019; 28:472-474, available at: http://dx.doi.org/10.1136/tobaccocontrol-2018-054518.

Further, FDA intends to prioritize enforcement of any ENDS product that is offered for sale after May 12, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

In addition to violations related to lack of marketing authorization, FDA will continue to take legal action regarding sales of tobacco products to minors and other violations and will closely monitor all sales of ENDS products.

1. Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored product)

FDA intends to prioritize enforcement for lack of marketing authorization against any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product) that is offered for sale in the United States without regard to whether or when premarket application for such product has been submitted.

In its balancing of the different public health considerations regarding ENDS products, the March 2019 Draft Guidance did not include tobacco-, mint- and menthol-flavored ENDS products in its proposed enforcement priorities, based on the data at that time indicating that these flavors were preferred more by adults than youth. The intent was, to the extent possible consistent with protecting population health, to avoid foreclosing one potential means by which some adult smokers might seek to transition completely away from combusted tobacco products to potentially less harmful tobacco products. Moreover, the March 2019 draft did not distinguish between cartridge-based products and other products, and instead focused on how products are sold rather than product characteristics.

As discussed above, evidence shows that youth are particularly attracted to flavored, cartridge-based ENDS products. Data show that, among youth who reported ever using an ENDS product, a large majority reported their first ENDS use was with a flavored ENDS product.[70] Data also show that among current youth ENDS users, a majority of youth respondents stated that they used ENDS products "because they come in flavors I like."[71] In addition, recent data indicate that flavors preferred by youth include mint. Data from the 2019 MTF survey indicate that youth use of mint- and fruit-flavored JUUL products is higher than that of menthol- and tobacco-flavored JUUL products.[72] Finally, data from the 2019 NYTS indicate that youth overwhelmingly prefer cartridge-based ENDS products.[73] These products are easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale.

[70] Rostron B et al. "Prevalence and Reasons for Use of Flavored Cigars and ENDS among US Youth and Adults: Estimates from Wave 4 of the PATH Study, 2016-2017," American Journal of Health Behavior, 44(1);76-81, 2020.

[71] *Id.*

[72] Leventhal A., et al., "Flavors of e-Cigarettes Used by Youths in the United States," JAMA, 322(21):2132-2134, 2019.

[73] Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21);2095-2103, 2019.

FDA received a number of comments that focused on the popularity of mint- and menthol-flavored ENDS among youth and adult populations. Some commenters suggested that such products would become even more popular if others became less available. They argued that not prioritizing enforcement against mint- and menthol-flavored ENDS products would risk the shift of youth from one flavor of ENDS products to another based on a potential but indeterminate impact on adult consumers. Several comments argued that data suggest that even if youth currently prefer "fruit" and "sweets" to mint and menthol, this does not mean that youth do not still find mint and menthol to be appealing flavors. FDA also received public comments claiming that mint- and menthol-flavored ENDS products help smoking cessation. For example, some commenters focused on the potential role that mint- and menthol-flavored ENDS products could play in helping some adults cease the use of combusted tobacco products.

It is possible that prioritizing enforcement against mint-flavored ENDS products could at least in the short term make fewer products available for some addicted adult smokers seeking to use ENDS products to transition completely away from cigarettes. However, the comments, as well as the recent surge in youth use of ENDS products, and especially the preferences indicated in the 2019 NYTS and 2019 MTF data, have led FDA to reconsider its approach with regard to prioritizing enforcement of mint-flavored ENDS products.

FDA also received multiple comments urging the Agency to further refine its enforcement priorities in consideration of how the design features of certain ENDS products may make them so popular among youth. Some commenters focused on the features of cartridge-based systems, particularly that they may contain high nicotine content and that they are easy to conceal. Similarly, some commenters focused on the potential impact of nicotine salts, which are used in some brands of cartridge-based ENDS products. In contrast, FDA received a comment arguing that the rise of youth use should not be attributed to all cartridge-based products but rather to a single, uniquely prevalent cartridge-based product, and that FDA's regulatory actions should be tailored accordingly.

As discussed above, data show that flavors are a strong driver for youth use, and that youth overwhelmingly use cartridge-based ENDS products. Moreover, preliminary research indicates that certain effects of nicotine salts in ENDS products (*e.g.*, higher nicotine exposure and faster rate of absorption) may increase the abuse liability of ENDS with nicotine salts, which raises concerns of addiction in youth, particularly due to the vulnerability of the developing adolescent brain. However, for many individual addicted cigarette smokers, the potential for ENDS to act as a substitute for cigarettes, thereby encouraging smokers to seek to switch completely away from combustible cigarettes, may be dependent, in part, upon the product having acceptability and abuse liability more comparable to a cigarette.

FDA has refined its enforcement priorities in the Final Guidance to focus on flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored). This approach strikes an appropriate balance between restricting youth access to such products, while maintaining availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from combusted tobacco products. FDA will, however, continue to evaluate new information and adjust these enforcement priorities, as warranted, in light of the best available data about these products.

We also note that the March 2019 Draft Guidance proposed to prioritize enforcement for flavored ENDS products that are offered for sale in ways that pose a greater risk for minors to access such products. Several comments discussed the wide availability of these products and the means by which youth gain access. These included comments that expressed concern regarding the availability of flavored ENDS products on the Internet and in vape shops. Other commenters focused on how the enforcement priorities were unclear and difficult for retailers to understand, and how that may negatively affect "potentially compliant" retail locations that attempt to prevent minor access. Others expressed concern that the enforcement priorities were altogether impractical and costly for retailers. While the March 2019 Draft Guidance proposed to focus its enforcement priorities of flavored ENDS products on how the product was sold, after considering the comments, the public health threats, and the new evidence described above, FDA determined that focusing on how the product was sold would not appropriately address youth use of the products that are the most popular among youth—*i.e.*, flavored, cartridge-based products. The reality is that youth have continued access to these products in the face of legal prohibitions and even after voluntary actions by some manufacturers. Moreover, as discussed above, the data show that youth overwhelmingly prefer certain flavors of cartridge-based ENDS products.[74] These products are produced on a large scale, are easy to conceal, can be used discreetly, and are not the products typically produced in vape shops that mix nicotine with e-liquid flavors. Given the urgent need to address the dramatic rise in youth use, this Final Guidance prioritizes enforcement with respect to any flavored, cartridge-based ENDS products (other than a tobacco- and menthol-flavored ENDS product) without regard to the location or method of sale. FDA believes that focusing enforcement on these products is important in addressing the increasing rates of youth use of these flavored, cartridge-based products because this is a primary driver in youth experimentation with, and continued use of, ENDS products.

Accordingly, FDA has recalibrated its balancing of public health considerations in light of the public health threats and the significant new evidence described above. This policy reflects FDA's balancing of concerns regarding the appeal of certain flavored, cartridge-based ENDS products to youth; the potential public health benefit of noncombusted options by which some adult smokers might seek to transition completely away from combusted tobacco products; and the potential risks created by extended availability of these new tobacco products without scientific review and evaluation under the applicable public health standard.

2. All other ENDS products without adequate measures to prevent minors' access

FDA intends to prioritize enforcement for lack of a marketing authorization for any other ENDS products (*i.e.*, any tobacco-, menthol-, or non-flavored ENDS products and any non-cartridge-based, flavored ENDS products) when the manufacturer has not taken or is not taking adequate measures to prevent minors' access to these products, without regard to whether or not, or when, a premarket application for such product has been submitted.

[74] Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21);2095-2103, 2019.

In assessing whether a manufacturer is taking (or has taken) adequate measures to prevent minors' access to these ENDS products, factors the Agency intends to consider include, but are not limited to:

- Whether the manufacturer has implemented adequate programs to monitor retailer compliance with age-verification and sales restrictions. Such programs might include, for instance: screening retailers, in advance of establishing or renewing distribution agreements, based on the strength of the retailers' age verification policies; establishing and publicizing a hotline for anonymous reporting of noncompliant sales; implementing a mystery shopper program; requiring use of technology that tracks age-verification practices; or other mechanisms.

- Whether the manufacturer has established and enforces penalties against retailers that fail to comply with age-verification and sales restrictions. For instance, in response to the September 12th letters, respondent manufacturers stated that they had mechanisms, such as through distribution agreements, to enforce financial penalties and stop sales to retailers in response to noncompliance. In addition to such mechanisms, FDA may consider whether a manufacturer has implemented a policy of notifying FDA of retailer violations.

- If the manufacturer is also a retailer, factors to adequately prevent underage access might include: whether the manufacturer/retailer has implemented programs to ensure compliance with age-verification and sales restrictions; establishing and publicizing a hotline for anonymous reporting of noncompliant sales; checking identification at the door; or other mechanisms.

- If the manufacturer is also a retailer, whether the manufacturer uses adequate age-verification technology (or requires that retailers who sell its products use such technology) to prevent underage access to its website and to prevent underage sales through the Internet. For instance, adequate age-verification could include use of an independent, third-party age- and identity-verification service that compares customer information against third-party data sources, such as public records; and

- Whether the manufacturer limits (or requires that retailers who sell its products to limit) the quantity of ENDS products that a customer may purchase within a given period of time.

FDA's decision to exercise its enforcement authorities with respect to particular products will be fact-specific and determined on a case-by-case basis.

This prioritization takes into account information that was provided by manufacturers in response to the Agency's September 2018 letters, including measures to address youth use that manufacturers can or have already taken to address youth access to ENDS products, as well as information provided in comments to the March 2019 Draft Guidance.

As noted, FDA considered comments about the practical concerns of implementing an enforcement policy based on how products are sold. The factors above reflect information FDA received from industry, including information manufacturers shared during meetings with FDA leadership, in response to the September 2018 letters, and public comments submitted in response to the March 2019 Draft Guidance. From this information, FDA understands that manufacturers have the means to monitor and/or control how their products are sold at retail by, for example, including or requiring terms, conditions, or controls in their contracts with downstream distributors (wholesalers, distributors, importers, and/or retailers) to prevent youth access.

The March 2019 Draft Guidance did not propose to prioritize enforcement for tobacco- or menthol-flavored ENDS products and did not propose to distinguish between cartridge-based and other ENDS products. The continued significant increase in youth use of ENDS, as demonstrated in the 2019 NYTS and MTF data, as well as the data showing that youth overwhelmingly use flavored, cartridge-based ENDS products, support a reconsideration of the Agency's approach. As noted in the draft guidance, FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, and it will continue to do so with respect to these unauthorized ENDS products.

As noted above, FDA received a number of comments arguing that the popularity of menthol-flavored ENDS (as well as mint-flavored ENDS, which are discussed above) had increased among youth and adult populations, and suggesting that such products would become even more popular if other flavored ENDS products became less available. They argued that excluding menthol-flavored ENDS products from prioritization would risk the shift of youth from one flavor of ENDS products to another based on a potential but indeterminate impact on adult consumers. FDA also received comments stating that it should immediately begin enforcing premarket review of all ENDS products, including tobacco-flavored ENDS products.

Other commenters emphasized a need for ENDS products to remain available for former smokers who have transitioned or current smokers who want to transition completely away from combustible products. Menthol is unique compared to other available ENDS product flavors as it is the only characterizing flavor available in cigarettes, and it may reduce the irritation and harshness of smoking.[75] Menthol cigarettes are also used by a substantial portion of the U.S. population, who are addicted to nicotine and may be looking for an alternative product to seek to transition completely away from combusted products.[76] FDA is compelled to act by data that

[75] *See, e.g.,* Harris, B., "Menthol: A review of its thermoreceptor interactions and their therapeutic applications," International Journal of Aromatherapy, 16(3-4):117-131, 2006; Galeotti, N., L.D. Mannelli, G. Mazzanti, et al., "Menthol: a natural analgesic compound," Neuroscience Letters, 322(3):145-148, 2002; Nishino, T., Y. Tagaito, Y. Sakurai, "Nasal inhalation of l-menthol reduces respiratory discomfort associated with loaded breathing," American Journal of Respiratory and Critical Care Medicine, 156(1):309-313, 1997; Lawrence, D., B. Cadman, A.C. Hoffman, "Sensory properties of menthol and smoking topography," Tobacco Induced Diseases, 9 Suppl 1(Suppl 1):S3, 2011; Garten, S. & R.V. Falkner, "Continual smoking of mentholated cigarettes may mask the early warning symptoms of respiratory disease," Preventive Medicine, 37(4):291-296, 2003.

[76] *See, e.g.,* United States Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and

show youth overwhelmingly prefer certain flavors of cartridge-based ENDS products such as fruit, mint, and candy.[77] At the same time, FDA is aware that approximately 9 million adults currently use e-cigarettes.[78] Studies have shown that the majority of adult e-cigarette users use flavored e-cigarettes and there is some evidence to suggest that flavored e-cigarettes may improve switching from cigarette smoking to using e-cigarettes, compared to non-flavored e-cigarettes.[79]

FDA seeks both (1) to avoid foreclosing, even if temporarily, one potential means by which some adult smokers might seek to transition completely away from combusted tobacco products to potentially less harmful tobacco products; and (2) to prevent minors' access to ENDS products. FDA believes that this policy strikes an appropriate balance between restricting youth access to ENDS products and maintaining availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from combusted tobacco products.[80]

Moreover, the prioritization of flavored, cartridge-based products articulated in Section D.1 above, and the prioritization of all other flavored ENDS product sold without adequate measures to prevent youth access, should have minimal impact on those vape shops that primarily sell non-cartridge-based ENDS products and that ensure purchasers are of the requisite age and not purchasing for resale (*e.g.*, are not purchasing in large quantities). Should evidence indicate to the contrary, the Agency will take appropriate action.

3. Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors

Many ENDS products have been and continue to be marketed to minors through a wide variety of media and technology, and their labels and labeling, print advertising, and/or online advertising are appealing to minors. Unlike combusted cigarettes and smokeless tobacco products, for which advertising through television and radio (and any other medium of electronic

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Health, 2016. Analysis run on October 12, 2018. SAMHSA's public online data analysis system (PDAS). (Original Data Source: NSDUH 2016)

[77] Cullen, K.A., A.S. Gentzke, M.D. Sawdey, "E-cigarette use among youth in the United States, 2019," JAMA, 322(21);2095-2103, 2019.

[78] Creamer, M.R., "Tobacco Product Use and Cessation Indicators Among Adults- United States 2018," Morbidity and Mortality Weekly Report, 68:1013-1019, 2019, available at: https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6845a2-H.pdf.

[79] Russell, C. et al. "Changing Patterns of First E-Cigarette Flavor Used and Current Flavors Used by 20,836 Adult Frequent E-Cigarette Users in the USA," Harm Reduction Journal, 15(1):33-47, 2018; Bonhomme, M.G. et al. "Flavoured Non-Cigarette Tobacco Product Use Among US Adults: 2013–2014," Tobacco Control, 25(Suppl 2):4–13, 2016.

[80] FDA notes that no ENDS product has been approved by FDA as a drug for smoking cessation. However, the premarket review process for ENDS products will provide an opportunity for FDA to further examine the potential of an ENDS product to meet the tobacco product premarket authorization standard of "appropriate for the protection of public health," including adult decisions to completely transition away from use of combustible products to potentially less harmful ENDS products or other non-combustible forms of nicotine delivery.

communication subject to regulation by the Federal Communications Commission) has been prohibited since 1971 and 1986 respectively,[81] ENDS products are advertised through television, radio, and online.[82] Social media accounts are frequently used to electronically share tobacco-product-related content with other minors.[83] Sales of such products to minors are prohibited, and FDA is concerned with actions likely to promote unlawful sales and maintain or increase youth use. FDA has issued joint warning letters with the FTC to four firms that manufacture, advertise and offer for sale or distribution several flavored e-liquid products for violations related to online posts by social media influencers on each company's behalf.[84] This type of marketing is especially concerning because longitudinal data from Waves 1 (2013-2014) and 2 (2014-2015) of the PATH Study show that engagement with online tobacco marketing is a risk factor for adolescent tobacco use, as adolescents who engaged with online tobacco marketing had greater incidences of initiating tobacco use, increased frequency of use and progression to poly-product use, and lower incidences of cessation compared to those who do not engage.[85]

Researchers have found that certain marketing strategies can increase youth appeal, both in general and with respect to tobacco products in particular. FDA has previously issued warning letters for products that resemble kid-friendly foods and drinks or that resemble other non-ENDS products that are often consumed by youth.[86] This includes labeling and/or advertising that results in the product resembling juice boxes, candy, or kid-friendly cereal. Actions by manufacturers to present their ENDS products in this way are likely to promote youth use, and also present a risk of confusion that could be harmful to children, including the risk of accidental poisoning.[87] Other marketing conduct likely to promote youth use includes the use of cartoons as part of e-cigarette manufacturers' and retailers' logos, marketing materials, promotions,[88]

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[81] 15 U.S.C. § 1335 ("It shall be unlawful to advertise cigarettes or little cigars on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission"); 15 U.S.C. § 4402(c) (same, for smokeless tobacco).

[82] U.S. Department of Health and Human Services, "E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General," 2016.

[83] *See* Chu, K.-H., J.B. Colditz, B.A. Primack, et al., "JUUL: Spreading Online and Offline," Journal of Adolescent Health, 63(5), 582-586, 2018.

[84] FDA News Release, "FDA, FTC take action to protect kids by citing four firms that make, sell flavored e-liquids for violations related to online posts by social media influencers on their behalf," June 7, 2019, available at: https://www.fda.gov/news-events/press-announcements/fda-ftc-take-action-protect-kids-citing-four-firms-make-sell-flavored-e-liquids-violations-related.

[85] Soneji, S., J. Yang, K.E. Knutzen, et al., "Online Tobacco Marketing and Subsequent Tobacco Use," Pediatrics, 141(2):e20172927, 2018; doi:10.1542/peds.2017-2927.

[86] *E.g.*, "E-Liquids Misleadingly Labeled or Advertised as Food Products," available at: https://www.fda.gov/tobaccoproducts/newsevents/ucm605729.htm; "FDA In Brief: FDA warns companies to stop making, selling or distributing e-liquids marketed to resemble prescription cough syrups," available at: https://www.fda.gov/news-events/fda-brief/fda-brief-fda-warns-companies-stop-making-selling-or-distributing-e-liquids-marketed-resemble.

[87] *See, e.g.,* Kamboj, A., H.A. Spiller, M.J. Casavant, et al., "Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States," Pediatrics, 2016;137(6):e2016004.

[88] Allem, J.-P., T. B. Cruz, J.B. Unger, et al., "Return of cartoon to market e-cigarette-related products," Tobacco Control, 0, 1-3, 2018; doi:10.1136/tobaccocontrol-2018-054437 (2018); Jackler, R. K., & Ramamurthi, D.,

Instagram posts,[89] and video advertisements.[90] Cartoon figures are frequently used on product packaging and in television advertising to promote youth consumption of consumer goods.[91] A common theme discussed in food and beverage industry publications has been using cartoons in marketing and packaging consumer products to target children and teenagers.[92] Another marketing strategy that has been recently employed by manufacturers is labeling, advertising, and/or product design that results in the ENDS product resembling ordinary items that may not draw the attention of adults.[93] Similar marketing conduct likely to promote youth use includes labeling and/or advertising highlighting how the product is 'stealth' or 'secret' and in the form of ordinary objects that may not be readily recognized by parents or teachers.[94]

Any efforts to entice minors to use tobacco products are of concern to FDA. FDA intends to prioritize its enforcement to focus on products that are targeted to minors or likely to promote use of ENDS by minors. Some examples of such products include:

- Products marketed with labeling and/or advertising that resemble kid-friendly foods and drinks or resemble other non-ENDS products that are often marketed and/or appealing to youth. This includes, for example, labeling and/or advertising that results in the product resembling juice boxes, candy, or kid-friendly cereal; and/or
- Products marketed directly to minors by promoting ease of concealing the product or the nature of the product as a tobacco product from parents, teachers, or other adults; and/or
- Products marketed with youth-appealing cartoon or animated characters, such as those that depict or resemble popular children's characters; and/or

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"Unicorns cartoons: marketing sweet and creamy e-juice to youth," Tobacco Control, 26(4), 471-475, 2017; doi:10.1136/tobaccocontrol-2016-053206; Kirkpatrick, M. G., T.B. Cruz, N.L. Goldenson, et al., "Electronic cigarette retailers use Pokémon Go to market products," Tobacco Control, 26(e2), e145, 2017; doi:10.1136/tobaccocontrol-2016-053369 (2017); Padon, A. A., E.K. Maloney & J.N. Cappella, "Youth-targeted e-cigarette marketing in the US," Tobacco Regulatory Science, 3(1), 95-101, 2017; doi:10.18001/TRS.3.1.9.

[89] Allem, J.-P., T.B. Cruz, J.B. Unger, et al., "Return of cartoon to market e-cigarette-related products," Tobacco Control, 0, 1-3, 2018; doi:10.1136/tobaccocontrol-2018-054437.

[90] Padon, A. A., Maloney, E. K., & Cappella, J. N., "Youth-targeted e-cigarette marketing in the US," Tobacco Regulatory Science, 3(1):95-101, 2017; doi:10.18001/TRS.3.1.9.

[91] Ethan, D., C.H. Basch, L. Samuel, et al., "An examination of product packaging marketing strategies used to promote pediatric multivitamins," Journal of Community Health, 40(3), 564-568, 2015; doi:10.1007/s10900-014-9972-1; Kraak, V. I., & Story, M., "Influence of food companies' brand mascots and entertainment companies' cartoon media characters on children's diet and health: a systematic review and research needs," Obesity Reviews, 16(2), 107-126, 2015.

[92] Barrey, S., M. Baudrin, & F. Cochoy, "From fun foods to fun stores," Young Consumers, 11(2);138-147, 2010; Cioletti, J., "Cereal thrillers," Supermarket Business Magazine, 56(10):30, 2001; Cioletti, J., "Future of... youth marketing," Beverage World, 122(8), 10 (2003); Cvetan, D., "Active market for active cultures," Dairy Field, 183(4):18, 2000; Fry, J., "Moo kids on the block say they've got more than the white stuff," Beverage World, 114(1596):1, 1995; Landi, H., "High Tea," Beverage World, 130(7):18-22, 2011; Steinriede, K., "The year's best packaging," Beverage Industry, 91(12): 34, 2000; White, L., "A license for profits," Professional Candy Buyer, 19(6):19-21, 2011.

[93] *See, e.g.,* Ramamurthi, D., C. Chau,, R.K. Jackler, "JUUL and Other Stealth Vaporisers: Hiding the Habit From Parents and Teachers," Tobacco Control, Sept. 2018, doi: 10.1136/tobaccocontrol-2018-054455.

[94] *Id*.

- Products marketed, including through paid social media influencers, with popular children's characters and titles (*e.g.*, popular children's YouTube channels, television shows, or characters). This includes, for example, the use of minors or people who portray minors on such shows and their associated show titles.

4. Any ENDS product that is offered for sale in the United States after May 12, 2020.

The U.S. District Court for the District of Maryland has ordered that premarket applications for all deemed new tobacco products on the market as of August 8, 2016, be submitted by May 12, 2020. Even in the absence of this court order, FDA would prioritize enforcement of any ENDS product that lacks a premarket application after May 12, 2020, for the reasons described in this guidance. For ENDS products other than those described in D.1 – D.3 above, if premarket applications are submitted by May 12, 2020, FDA intends to continue to exercise enforcement discretion for up to one year pending FDA review, unless there is a negative action by FDA on such application. A negative action would consist of the issuance of a Refuse to Accept (RTA), Refuse to File (RTF), and/or No Marketing Order (NMO); or of a letter administratively closing the application, or cancelling the application if FDA finds that it mistakenly accepted the application or that the application was submitted in error. In addition, the other enforcement priorities discussed in this guidance would apply to such products, regardless of whether or not a premarket application has been submitted for the product.

We note that the March 2019 Draft Guidance had included August 8, 2021, as the date for which FDA would prioritize enforcement for flavored ENDS products that had not submitted premarket applications. A number of comments expressed concern about the impact of the August 2021 date on businesses. For example, several commenters argued that any restriction on the sale or distribution of ENDS products could result in companies going out of business. On the other hand, FDA received many comments suggesting that in light of the problem of increasing youth access and use of ENDS products, FDA should begin enforcing the premarket authorities as applied to deemed new tobacco products earlier than August 8, 2021. Several comments remarked that FDA should have begun enforcing the premarket review requirements against ENDS products already, that FDA's previous premarket review compliance date extensions enabled some companies to "delay or circumvent areas of regulatory compliance," and that further delays were contrary to public health.

Although FDA considered the potential impact of the draft compliance policy on businesses large and small, we note that, pursuant to the Tobacco Control Act, as of the effective date of the final deeming rule, ENDS products were required to have premarket authorization prior to marketing. While some deemed new tobacco products remained on the market in light of FDA's deferred enforcement policy, such policies are subject to change. Manufacturers cannot have settled expectations to market unlawful products, especially in the face of evolving public health concerns. Therefore, FDA believes that manufacturers should have begun contemplating and/or preparing premarket applications no later than the time of the final deeming rule. As discussed in Section II.B of this Final Guidance, FDA has repeatedly publicly discussed the fact that enforcement discretion timelines for deemed tobacco products were under reconsideration and solicited views from stakeholders. Manufacturers may obtain information about the application

process from the statutory criteria, as well as published guidances, webinars, and marketing orders and their accompanying documentation provided by FDA.[95]

Under the circumstances, FDA believes that earlier enforcement of the premarket review provisions is appropriate for ENDS products. This policy should result in earlier submission of applications and allow FDA to better evaluate whether these products meet the applicable premarket standard, such as whether the products are appropriate for the protection of the public health, considering the risks and benefits to the population as a whole, including users and nonusers of the tobacco product. Because of FDA's concerns regarding youth use of ENDS products, as well as other ongoing health concerns regarding vaping more generally, all described at length above, FDA is prioritizing enforcement of premarket review requirements for ENDS products, as described in this section, and is doing so independently of the court order. This will ensure that FDA has the necessary information to exercise adequate, timely oversight over these relatively novel and potentially harmful products. Enforcing premarket authorization requirements will, consistent with the process set forth in the Tobacco Control Act, ensure that the burden falls on manufacturers of ENDS products to demonstrate that the manufacture and sale of their products is appropriate for the protection of the public health.

E. Avoiding a "Black Market"

FDA is aware of concerns that, given the rise in popularity of ENDS, removal of some of the most popular products from the market may be accompanied by an increase in black market versions of these products that may pose additional health and safety risks to consumers beyond those of the authentic products. Although all newly deemed products currently on the market without premarket authorization are being sold in violation of the Tobacco Control Act, in this section, we use the term "black market" to refer to, for example, products intended to look like another ENDS products that is currently being marketed, products intended to take the place of an ENDS product that a manufacturer has stopped distributing because the product lacks premarket authorization, and ENDS products intended for another country's market but diverted to the U.S. market. Additional risks posed by these products include the potential that they contain harmful chemicals or constituents that are not present in other products, that they are manufactured using comparatively poor quality controls, and that they are designed in ways that facilitate modifications by distributors or users—all of which increase the risk of adverse events.[96] Moreover, to the extent that such products are sold through nontraditional retail

[95] For more information on premarket tobacco product applications please see Premarket Tobacco Product Applications for [ENDS], Guidance for Industry (June 2019), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends; Applications for Premarket Review of New Tobacco Products (updated June 2019) available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-premarket-review-new-tobacco-products. For more information on CTP's other published regulations and guidances, please see https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance; for more information on FDA CTP webinars, please see https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars; for information on marketing orders and accompanying documentation, please see https://www.fda.gov/tobacco-products/compliance-enforcement-training.

[96] *E.g.*, "Amid Vaping Deaths, California Targets Counterfeit Products," The New York Times (Sept. 17, 2019), available at https://www.nytimes.com/2019/09/16/us/california-vaping.html; "'Juul-alikes' Are Filling Shelves With

channels, such as social sources or online commercial marketplaces that do not include age-verification requirements, they pose an increased risk of being accessed by minors.

FDA has regulatory tools and enforcement authorities to address ENDS and other tobacco products that are marketed without authorization, that are counterfeit, and/or that are otherwise involved in illicit trade.[97] FDA has previously issued letters to companies suspected of marketing counterfeit or otherwise unauthorized products.[98] Additional potential actions against adulterated or misbranded illicit tobacco could include: (1) issuing a Warning Letter; (2) issuing an import alert and refusing admission of tobacco products imported or offered for import into the United States; and (3) initiating seizure or injunction court actions. Persons engaging in illicit trade in tobacco products may also be criminally prosecuted under the law.

As a result of this policy, FDA will be better situated to combat black market products, including those that are particularly troubling from a public health or safety perspective, such as counterfeit pods entering the country at the border or being sold through illicit, online channels. By prioritizing our focus as outlined in Section IV.D, the Agency can target our supply chain surveillance and investigation resources on the types of ENDS products that are likely to be subject to counterfeiting and/or sale on the black market. As a result, we will be able to more efficiently and effectively deploy our enforcement tools to get counterfeit and black market products off the market. Moreover, FDA believes that there are significant public health benefits of the policy set forth in this guidance, which is aimed at curbing the dramatic rise in youth use of ENDS products and will help address safety issues connected to ENDS products that are not fully understood—*e.g.*, the development of acute or chronic lung injuries associated with use of vaping products as well as battery explosions with ENDS products—particularly given that these products have been marketed without premarket evaluation. These current public health issues affirm the importance of the premarket review process, as contemplated by the Tobacco Control Act, to scientifically evaluate products based on a public health standard.

V. PREMARKET REVIEW FOR OTHER DEEMED NEW TOBACCO PRODUCTS

FDA remains concerned with minors' access to and use of all tobacco products, particularly flavored tobacco products, which appeal to minors and promote initiation.[99] In addition to the

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Sweet, Teen-Friendly Nicotine Flavors" The New York Times (Aug. 13, 2019), available at https://www.nytimes.com/2019/08/13/health/juul-flavors-nicotine.html; Omaiye, E.E., I. Cordova, B. Davis, et. al., "Counterfeit Electronic Cigarette Products with Mislabeled Nicotine Concentrations," Tobacco Regulatory Science, 3(3): 347–357, 2017.

[97] *See, e.g.*, sections 301, 902, 903, 905, 910, and 920 of the FD&C Act.

[98] *E.g.*, "Statement from FDA Commissioner Scott Gottlieb, M.D., on forceful new actions focused on retailers, manufacturers to combat youth access to e-cigarettes as part of FDA's Youth Tobacco Prevention Plan," available at: https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-forceful-new-actions-focused-retailers-manufacturers.

[99] U.S. Department of Health and Human Services, "E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General," 2016; Villanti, A.C., A.L. Johnson, B.K. Ambrose, et al., "Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014)," American Journal of Preventive Medicine, 53(2); 139-151, 2017.

tobacco products covered earlier in this guidance document, FDA has considered revising its enforcement priorities with respect to premarket authorization for other deemed new tobacco products. We note that several comments on the March 2019 Draft Guidance suggested that FDA begin immediately enforcing the premarket requirements for flavored deemed tobacco products such as cigars and other deemed tobacco products.

FDA received numerous comments relating to the proposed policy for flavored cigars in the March 2019 Draft Guidance. Some of the comments were supportive of that proposed policy, although some wanted the Agency to take even more aggressive action. Other comments opposed inclusion of flavored cigars as an enforcement priority and disagreed with the bases for the proposed policy. For example, some commenters argued that flavored cigars are used most commonly by adult users and that the inclusion of flavored cigars as an enforcement priority limits adults' freedom to choose their preferred product. Other commenters argued that FDA did not have the data necessary to support the need for "a drastic and unprecedented change in enforcement priorities." Some commenters also stated that the evidence cited by FDA discussing initiation of youth usage of flavored cigars was inconsistent and inconclusive. After consideration of the data regarding youth use of cigars generally and comments received on this issue, we have decided to not prioritize enforcement of flavored cigars before May 12, 2020. While there is no public health benefit associated with flavored cigars and FDA remains concerned with youth use of flavored cigars, current data indicate that youth are using flavored cigars at a lower rate than they are using flavored ENDS products.

Comments regarding deemed tobacco products other than ENDS products and cigars, such as waterpipe tobacco (hookah) products, also provided data showing the use of such tobacco products among high school students and stating that evidence reflects that flavors for these tobacco products entice youth. However, such data do not appear to raise comparably urgent public health concerns, as the lower prevalence of youth use of these products suggests that they do not appear to be as appealing to youth at this time.

Accordingly, at this time, FDA has decided to prioritize use of its limited enforcement resources to address the sudden and dramatic increase in youth use of ENDS products, as well as to focus on health and safety concerns connected to ENDS products such as vaping-associated lung injuries. While acknowledging that all new tobacco products on the market without the required authorization are marketed unlawfully and are potentially subject to enforcement action, at any time, in FDA's discretion, FDA's primary focus will be to address the sudden and dramatic increase in youth use of ENDS products, and the products covered by this section of the guidance will therefore be a lower priority.

We have decided not to prioritize enforcement of the tobacco products covered by this section before May 12, 2020. Manufacturers of flavored cigars, however, just like manufacturers of all other deemed new tobacco products, will be required to submit marketing applications for those products by May 12, 2020, consistent with the U.S. District Court for the District of Maryland's order directing FDA to require that applications be submitted to the Agency by May 12, 2020, for deemed new tobacco products on the market as of August 8, 2016, or be subject to FDA enforcement actions, in FDA's discretion. As part of the premarket review process, FDA may evaluate, among other things, the product's constituents, ingredients, additives, and properties;

manufacturing practices; and any studies or investigations into the health risks of the tobacco product. FDA also has stated its intention to issue a regulation that would ban the use of characterizing flavors in cigars, and FDA is actively working towards that proposed rule.

After May 12, 2020, FDA will make enforcement decisions on a case-by-case basis, recognizing that it is unable, as a practical matter, to take enforcement action against every illegally marketed tobacco product, and that it needs to make the best use of Agency resources. FDA intends to prioritize enforcement based on the likelihood of youth use or initiation to make the most efficient use of its resources. In assessing this, factors the Agency intends to consider include, but are not limited to:

- What FDA understands about the number of youth currently using the product or category of product;
- The trends in those numbers, particularly since 2016;
- Whether the product contains added flavors;
- What FDA understands about how the product or category of product is typically sold and how that is likely to impact access and use by minors; and
- What FDA understands about the frequency and other demographics of use by minors.

To illustrate, based on these factors, FDA's lowest priority among these products will include relatively expensive, large hand-rolled cigars that do not have flavors (*e.g.*, fruit, candy, or mint), given what FDA understands to be their comparatively lower youth usage rates.

* * *

FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, and it will continue to do so with respect to these products. FDA will take appropriate action regarding tobacco products that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors' use of those products.

APPENDIX A – SIGNIFICANT COMMENTS RECEIVED IN RESPONSE TO MARCH 2019 DRAFT GUIDANCE AND FDA RESPONSES

Legal and statutory framework issues	
Comment	Response
FDA should engage in legislative rulemaking process • The draft guidance constituted a major rule and FDA has not followed procedures established by the Administrative Procedure Act (APA) governing the promulgation of rules • The Regulatory Flexibility Act requires an analysis of a proposed rule's impact on small business and FDA has not conducted such an analysis • FDA is bypassing the requirement to conduct a cost benefit analysis by issuing a guidance instead of formal rule • FDA has not considered regulatory alternatives to the approach outlined in the draft guidance • This action would impose costs and adverse effects on industry which constitutes a major rule which should be subject to the requirements under the Congressional Review Act • Though guidance documents are non-binding, the way the guidance is written, retail outlets would need to comply with standards suggested by the draft guidance as though they were law • Engaging in rulemaking would offer more substantial opportunity for stakeholders to provide public comments and would provide clarity on what stakeholders (through the supply and retail chain) needed to do to come into compliance	The Final Guidance is a statement of policy that discusses the enforcement of premarket authorities already existing in the statute. It does not establish any rights for any person, is not binding on FDA or the public, and is not subject to requirements of the Regulatory Flexibility Act or the notice-and-comment provisions of the APA. Historically, FDA has not analyzed the economic effects of enforcement guidance, including for reasons such as difficulty in predicting such effects. Alternatives such as issuing warning letters and other enforcement techniques have been considered and used by the Agency. Despite this, as shown by the data highlighted in the Final Guidance, the rate of youth use of tobacco products (particularly fruit- and candy-flavored and mint-flavored ENDS products) has dramatically increased. FDA retains discretion to enforce premarket authorities. The relevant substantive requirements are those governing premarket authorization as set forth in Section 910. The Final Guidance does not impose new restrictions, for retailers or manufacturers, but rather discusses FDA's enforcement priorities for existing statutory requirements. In Section 910, Congress placed the onus on manufacturers to demonstrate that the marketing of a tobacco product is appropriate for the protection of the public health, taking into account, among other things, the likelihood that those who do not use tobacco products will start using them. FDA provided for a 45-day period for comment on the draft guidance, and interested parties may continue to submit comments after publication of the final guidance, providing a substantial opportunity for public input.
FDA is bypassing statutory restrictions on its discretionary enforcement authority and obligations related to rulemaking, by	FDA has discretion to decide how when to enforce its premarket authorization authorities under the FD&C Act. *See Heckler v. Chaney*, 470 U.S. 821,

threatening selective enforcement of its premarket authorization authority.	835 (1985). The Final Guidance is a statement of policy that outlines FDA's enforcement priorities with respect to such requirements.
Guidance should conform to Section 907. • Actions in this guidance should conform to Section 907, which obligates FDA to consider factors not addressed by the guidance, including technical achievability and countervailing effects. • FDA should not adopt modifications to compliance policy but should instead follow through with a rule that considers the comments from FDA's ANPRM on Flavors in Tobacco Products.	Section 907 refers to tobacco product standards. This Final Guidance is not setting tobacco product standards, such as a tobacco product standard restricting or eliminating the use of flavors in ENDS. Instead, it is explaining FDA's enforcement priorities for premarket review requirements already included in the Tobacco Control Act. A flavored product could be marketed consistent with this guidance if it meets the statutory standards for authorization. For example, in April 2019, FDA authorized the marketing of a menthol-flavored IQOS heat-not-burn cigarette product through the PMTA pathway.[100]
FDA is supposed to be an advisory agency, not a regulatory agency, and its actions are an overreach.	The Tobacco Control Act provides FDA with regulatory authority over tobacco products.
FDA's proposed actions are arbitrary and capricious because it has failed to provide adequate reasoning/scientific reasoning/used incomplete or incorrect data.	The enforcement priorities explained in the Final Guidance are based upon and supported by, among other things, multiple high-quality scientific data sources (*e.g.*, NYTS, PATH, MTF).
FDA has failed to connect the proposed policy to an official finding that the actions were "appropriate for the protection of public health."	The Final Guidance discusses the enforcement of premarket authorities already existing in statute. Section 910 places the onus on manufacturers to show that the marketing of a tobacco product would be appropriate for the protection of the public health, not on the FDA to show otherwise. The Tobacco Control Act uses the term "appropriate for the protection of the public health," in section 910 and several other provisions. The considerations identified in the statute typically include analysis of whether the action would increase or decrease the likelihood that existing users of tobacco products would stop using such products, and whether it would increase or decrease the likelihood that those who do not

[100] For more information please see https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway.

	use tobacco products will start using the products. The Guidance reflects these considerations.
FDA has been unresponsive/lack of clarity. • Manufacturers have been relying on guidance and information since the deeming rule; this is a drastic departure from deeming and guidances issued since deeming. • Difficult to keep track of FDA's policies and compliance requirements.	FDA has communicated its concerns regarding the increase in youth access in public statements, the March 2019 draft guidance, and requests for information to manufacturers. FDA has consistently informed industry that its compliance policies will be responsive to changed circumstances. There could be no reasonable reliance on a deferred enforcement policy subject to change at any time. The guidance explains why the changed circumstances warrant this prioritization; *i.e.*, the substantial increase in youth use of ENDS in addition to other health and safety considerations. FDA has always stated (and the Tobacco Control Act itself is clear) that deemed new tobacco products are required to obtain premarket authorization and that such products that remain on the market without marketing authorization are marketed unlawfully.
FDA has stated it will provide further guidance and issue rules to make the product review process more transparent and predictable but has not done so.	FDA has provided guidance and information to industry on the premarket pathways through publishing guidances and marketing orders, as well as posting information via webinars and public workshops.[101] The statute also informs the public of the information needed in a premarket tobacco product application. Industry members have successfully obtained marketing authorization orders with information currently available.
Draft guidance would have unjustifiable retroactive effects on industry actors who were "in compliance" with FDA's previous policy.	This Final Guidance would only affect those products that are illegally on the market; none of the products affected by the guidance were ever in compliance with the premarket authorization requirements of the law. FDA has consistently

[101] For more information on premarket tobacco product applications please see Premarket Tobacco Product Applications for [ENDS], Guidance for Industry (June 2019), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends; Applications for Premarket Review of New Tobacco Products (updated June 2019) available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-premarket-review-new-tobacco-products. For more information on CTP's other published regulations and guidances, please see https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance; for more information on FDA CTP webinars, please see https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars; for information on marketing orders and accompanying documentation, please see https://www.fda.gov/tobacco-products/compliance-enforcement-training.

	informed industry that its compliance policies will be responsive to changed circumstances. As discussed in the guidance, FDA stated in the notice of proposed rulemaking for the Deeming Rule, that the overall public health impact of ENDS products would depend crucially upon "who uses the products and how they are used. If such products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is a potential for the net impact at the population level to be positive. If, on the other hand, there is significant initiation by youth, minimal quitting, or significant dual use of combust[ed] and non-combust[ed] products, then the public health impact could be negative." As such policies are subject to change, manufacturers cannot have settled expectations to market unlawful products, especially in the face of evolving public health concerns. Therefore, FDA believes that manufacturers should have begun contemplating and/or preparing premarket applications at no later than the time of the final deeming rule.
Draft guidance will kill innovation and force industry out of work.	FDA disagrees that the Final Guidance will cause these results. The Final Guidance explains FDA's enforcement priorities for certain deemed new products that are being marketed without required premarket tobacco product authorization. The Final Guidance would only affect those products that are illegally on the market; none of the products affected by the guidance were ever in compliance with the premarket authorization requirements of the law. In any event, FDA believes that the use of premarket pathways will incentivize development of innovative tobacco products that meet the applicable statutory standards.
Draft guidance policy on marketing practices would violate the First Amendment as it represents an impermissibly broad commercial speech restriction.	FDA disagrees that the Final Guidance violates the First Amendment. Speech regarding an illegal activity – including distribution of a product that requires premarket review under the FDCA – is not protected under the First Amendment. *See United States v. Caputo*, 517 F.3d 935, 941 (7th Cir. 2008) (unapproved device); *United States v. LeBeau*, 654 Fed. App'x 826, 831 (7th Cir. 2016)

	(unapproved drug); *United States v. Cole*, 84 F. Supp. 3d 1159, 11-66-67 (D. Or. 2015) (unapproved drug). Even if the First Amendment were applicable, the government has a substantial interest in protecting youth from tobacco products, and prioritizing enforcement actions with respect to ENDS products targeted to, or likely to promote use by, minors is a reasonable measure to directly advance that interest. *See, e.g.*, *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 536 (6th Cir. 2012). We have provided additional examples for clarity in the Final Guidance.
Modifications to ENDS Compliance Policy – Flavored ENDS except Tobacco, Mint, Menthol	
Comment	Response
There is no evidence/limited evidence to connect liquid nicotine use with harmful health effects in youth.	As discussed in the Final Guidance the studies of the effects of nicotine exposure in the naïve adolescent brain find that the adolescent brain is uniquely vulnerable to nicotine compared to the adult brain. Repeated exposure to nicotine during adolescence induces long-lasting structural and functional changes in brain regions involved in addiction, attention, learning, and memory.[102] Studies further suggest that nicotine-induced changes in the adolescent brain can lead to long-lasting effects on cognitive function, such as cognitive deficits following nicotine abstinence, and may contribute to the risk for mood and anxiety disorders. Nicotine is the primary addictive substance in tobacco products, including e-cigarettes and combustible cigarettes. The rate and extent of nicotine delivery significantly impact product abuse liability. Higher nicotine content and faster rates of nicotine delivery increase products' abuse liability due to the rapid absorption of nicotine into the brain. Some e-

[102] McDonald, C.G., A.K. Eppolito, J.M. Brielmaier, et. al., "Evidence for elevated nicotine-induced structural plasticity in nucleus accumbens of adolescent rats," Brain Research, 1151, 211-218, 2007; doi: 10.1016/j.brainres.2007.03.019; Bergstrom, H.C., R.F. Smith,, N.S. Mollinedo, et al., "Chronic nicotine exposure produces lateralized, age-dependent dendritic remodeling in the rodent basolateral amygdala," Synapse, 64(10), 754-764, 2010; doi:10.1002/syn.20783; England, L.J., K. Aagaard, M. Bloch, et al., "Developmental toxicity of nicotine: a transdisciplinary synthesis and implications for emerging tobacco products," Neuroscience and Biobehavioral Reviews, 72:176-189, 2017.

	cigarettes are capable of achieving similar or greater nicotine delivery as cigarettes.[103]
"Banning" flavors outside of tobacco, mint, and menthol would deter cigarette smokers from quitting or force smokers to restart smoking if they have already quit. • Smokers trying to quit smoking avoid tobacco-, mint-, and menthol-flavored products because they are too similar to flavors of a traditional cigarette. • Stricter policies for ENDS products for youth should not come at expense of adult users.	The Final Guidance does not ban any products but rather identifies FDA's priorities in connection with the enforcement of the statutory premarket review requirements. Moreover, the policy announced in the Final Guidance does not prioritize any menthol-flavored, tobacco-flavored, or non-flavored ENDS products or any non-cartridge-based flavored ENDS products for enforcement where the manufacturer is taking adequate measures to prevent minors' access to these products. Additionally, consumers will be able to access ENDS products (including flavored ENDS products) that receive market authorization. Nicotine replacement therapy products also remain available for tobacco product users who may need assistance with withdrawal symptoms and are also available in several flavors. Available research does not support the argument that smokers trying to quit smoking and transition to ENDS products avoid tobacco and menthol-flavored ENDS products because they are too similar to traditional cigarette flavors. FDA has repeatedly emphasized that the availability of non-combustible options should not come at the expense of addicting a generation of children to nicotine through these same delivery vehicles. FDA believes that this policy strikes an appropriate balance between preventing youth

[103] Hiler, M., A. Breland, T. Spindle, et al., "Electronic cigarette user plasma nicotine concentration, puff topography, heart rate, and subjective effects: Influence of liquid nicotine concentration and user experience," Experimental and Clinical Pharmacology, 25(5), 380-392, 2017; doi:10.1037/pha0000140; Lopez, A.A., M.M. Hiler, E.K. Soule, et al., "Effects of Electronic Cigarette Liquid Nicotine Concentration on Plasma Nicotine and Puff Topography in Tobacco Cigarette Smokers: A Preliminary Report," Nicotine & Tobacco Research, 18(5):720-723, 2016; doi:10.1093/ntr/ntv182; Maloney, S. F., A. Breland, E.K. Soule, et al. "Abuse liability assessment of an electronic cigarette in combustible cigarette smokers," Experimental and Clinical Psychopharmacology, 27(5):443-454, 2019; doi:10.1037/pha0000261; O'Connell, G., J.D. Pritchard, C. Prue, et al, "A randomised, open-label, cross-over clinical study to evaluate the pharmacokinetic profiles of cigarettes and e-cigarettes with nicotine salt formulations in US adult smokers," Internal and Emergency Medicine, 14(6):853-861, 2019; doi:10.1007/s11739-019-02025-3; Ramoa, C. P., M.M. Hiler, T.R. Spindle, et al. "Electronic cigarette nicotine delivery can exceed that of combustible cigarettes: a preliminary report," Tobacco Control, 25(e1): e6-9, 2016; doi:10.1136/tobaccocontrol-2015-052447; Yan, X. S., & C. D'Ruiz, "Effects of using electronic cigarettes on nicotine delivery and cardiovascular function in comparison with regular cigarettes," Regulatory Toxicology and Pharmacology, 71(1):24-34, 2015; doi:10.1016/j.yrtph.2014.11.004.

	access to ENDS products and maintaining availability of potentially less harmful options for current adult smokers who have transitioned or wish to transition completely away from combusted tobacco products.
No basis for prioritizing flavored ENDS products. • The policy will not be successful at keeping kids from using these products; kids use anything that is taboo and illegal. • Youth are more attracted to these products due to peer use than flavors. • Youth use ENDS products for nicotine delivery not for flavors. • Only a correlative, not causal, relationship between youth preference for flavors and increased ENDS usage.	As discussed in the Final Guidance, data from 2018 NYTS as well as from 2019 Monitoring the Future study and 2019 NYTS show a significant increase in youth use of these products. Data also clearly show that flavors are a primary driver in youth experimentation with, and continued use of, ENDS products, and that the flavored ENDS products overwhelmingly used by youth are cartridge-based products. The policy outlined in the Final Guidance prioritizes enforcement of ENDS products that are targeted to minors or likely to promote use of ENDS by minors. FDA expects that this policy and others stated in the guidance will make fewer products available and more difficult for youth to obtain.
No basis for excluding tobacco, mint, and menthol from prioritization. • General increasing popularity of mint and menthol ENDS products amongst youth populations. • Mint- and menthol-flavored products drive youth ENDS usage. • Flavors clearly increase appeal of ENDS products and some flavors have toxic effects and documented respiratory toxicity.	The Final Guidance explains that FDA intends to prioritize mint-flavored, cartridge-based ENDS products (and any other flavored, cartridge-based ENDS product, other than tobacco- or menthol-flavored ENDS products) for enforcement for lack of a marketing authorization. The guidance also explains that FDA intends to prioritize enforcement for lack of a marketing authorization for any tobacco- or menthol-flavored ENDS products and non-cartridge-based flavored ENDS products when the manufacturer is not taking adequate measures to prevent minors' access to these products. Data shows that tobacco- and menthol-flavored ENDS products are not as appealing to minors as other flavored ENDS products. While the NYTS groups mint- and menthol-flavored products together, a randomly-selected third of respondents to the Monitoring the Future (MTF) study were asked specifically about their preferred flavors of JUUL and reported use of menthol- and tobacco-flavored products were among the lowest ranked options. Based on the available data and FDA's interest in balancing between preventing youth usage and preserving options for adults trying to transition away from

	combustible products, FDA is not prioritizing enforcement against tobacco-, menthol-, and non-flavored ENDS products or non-cartridge-based flavored ENDS products except when the manufacturer is not taking adequate measures to prevent minors' access to these products.
Prioritizing flavors for enforcement will create a significant black market for "banned" flavors outside those that are exempted.	By black market flavored products, we assume this could refer to, for example, flavored ENDS products, including e-liquids, put on the market after the guidance, flavored ENDS products diverted from another country's market to the U.S market, and/or flavored ENDS products made to look like another ENDS product that is currently being marketed. FDA has regulatory tools and enforcement authorities to address deemed tobacco products that are marketed without authorization, counterfeit, and/or otherwise involved in illicit trade. *See, e.g.*, sections 301, 902, 903, 905, 910, and 920 of the FD&C Act. This Final Guidance describes the Agency's enforcement priorities for products that are on the market without the required premarket authorization—it does not ban any tobacco product—and illicit ENDS products are necessarily subject to the enforcement priorities identified in the guidance as they do not have premarket authorization. Thus, FDA believes that this policy will not significantly increase illicit practices or create new illicit markets, and it could help FDA better address such practices. Once products receive premarket authorization, they can legally enter the market. FDA believes that there are significant public health benefits of the policy set forth in the guidance, which is aimed at curbing the dramatic rise in youth use of ENDS products and will help address safety issues connected to ENDS products that are not fully understood—*e.g.*, lung injuries associated with use of vaping products as well as battery explosions with ENDS products—particularly given that these products have been marketed without premarket evaluation. These current public health issues affirm the importance of the premarket review process, as contemplated

	by the Tobacco Control Act, to scientifically evaluate products based on a public health standard. FDA believes that by pursuing this policy the Agency will be better able to monitor and identify illicit cartridge-based products that are threats to public health and safety. As flavored, cartridge-based products exit the market until they are able to demonstrate that they meet the applicable public health standard and receive authorization, the number of potential flavored, cartridge-based products that could cause these threats will shrink to a more manageable number for FDA to monitor. Thus, FDA expects that to the extent any illicit markets were to develop with respect to cartridge-based products in an attempt to evade premarket review requirements, this guidance will help FDA better address the public health threats caused by such markets and the overall public health benefits that will likely accrue as a result of the guidance will be greater than any negative effects of increased illicit markets. Moreover, FDA does not believe that the Agency should refrain from enforcing existing statutory authorities merely because regulated entities could find other ways to violate such authorities. The Agency can, and will, continue to monitor the marketing and use of ENDS and other tobacco products, and adjust its policies and approaches as warranted.
Many other harmful products (*e.g.*, alcohol) are available in various flavors attractive to youth; it is inconsistent to only prioritize for enforcement flavored ENDS products.	The policy expressed in this Final Guidance is limited solely to tobacco products over which FDA has statutory authority. The focus of this guidance and the Agency's enforcement priorities is tobacco products, specifically certain ENDS products. Moreover, this comment is about flavored alcohol products that are lawfully on the market, whereas this guidance concerns products being sold in violation of the requirement to have premarket authorization, where the product's ingredients and additives are among the considerations in the premarket review.
FDA should focus its enforcement priorities on products that contain nicotine salts and/or should specify differences between nicotine and nicotine salts.	FDA believes that ENDS products containing nicotine salts will be adequately addressed by the enforcement priorities set in this Final Guidance.

	Research is ongoing to better understand the abuse liability associated with nicotine-salt based e-liquids and new cartridge-style ENDS products, the potential for initiation in youth and nonusers, and the potential for switching from combusted cigarettes in current smokers from use of these products. Preliminary research indicates that nicotine salts in ENDS products can drive nicotine exposures in users higher than ENDS containing freebase nicotine; these exposures can also be comparable to or potentially higher than cigarettes.[104] In addition to greater nicotine exposures, ENDS with nicotine salts can have faster absorption[105] and potentially faster elimination from the blood.[106] These factors can increase the abuse liability of ENDS with nicotine salts compared to freebase nicotine, and potentially cigarettes. The higher abuse liability of ENDS with nicotine salts compared to freebase nicotine raises concerns of addiction in youth, particularly due to the vulnerability of the developing adolescent brain. However, for many individual addicted cigarette smokers, the potential for ENDS to act as a substitute for cigarettes, thereby encouraging smokers to seek to switch completely away from combustible cigarettes, may be dependent, in part, upon the product having acceptability and abuse liability more comparable to a cigarette. The Final Guidance focuses FDA's priorities on flavored, cartridge-based ENDS products because

[104] Goniewicz, M. L., R. Boykan, C.R. Messina, et al., "High exposure to nicotine among adolescents who use Juul and other vape pod systems ('pods')," Tobacco Control, 28(6), 2019; doi:10.1136/tobaccocontrol-2018-054565; Talih, S., R. Salman, R. El-Hage, et al, "Characteristics and toxicant emissions of JUUL electronic cigarettes," Tobacco Control, 28(6):678-680, 2019; doi:10.1136/tobaccocontrol-2018-054616; Teichert, A., P. Brossard, L.F. Medlin, et al, "Evaluation of Nicotine Pharmacokinetics and Subjective Effects following Use of a Novel Nicotine Delivery System," Nicotine Tobacco Research, 20(4):458-465, 458-465; doi:10.1093/ntr/ntx093.

[105] O'Connell, G., J.D. Pritchard, C. Prue, et al., "A randomised, open-label, cross-over clinical study to evaluate the pharmacokinetic profiles of cigarettes and e-cigarettes with nicotine salt formulations in US adult smokers," Internal and Emergency Medicine, 14:853-861, 2019; doi:10.1007/s11739-019-02025-3.

[106] Bowen, A., & C. Xing, "Nicotine Salt Formulations for Aerosol Devices and Methods Thereof," United States Patent, Pub. No. US 2015/0020824, 2015, https://patentimages.storage.googleapis.com/57/f8/7e/2db69f396801d5/US20150020824A1.pdf (visited Oct 8 2019).

	data show that flavors are a strong driver for youth use, and that youth overwhelmingly prefer cartridge-based ENDS products. However, FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, including any data on ENDS products containing nicotine salts, and it will continue to do so with respect to these products.
FDA should focus its enforcement priorities on cartridge-based ENDS products.	FDA is concerned about the rising youth appeal and use of ENDS products. The data show that flavors are a strong driver for youth use, and that youth overwhelmingly use cartridge-based ENDS products. Accordingly, such products are a key focus of the Final Guidance. FDA will, however, take appropriate action regarding ENDS that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors' use of those products.
Modifications to ENDS Compliance Policy – Offered for sale in ways that pose a greater risk for minors to access such products	
Comment	Response
The Tobacco Control Act prohibits FDA from restricting tobacco sales to a specific category of retail outlets.	FDA is not restricting or even prioritizing enforcement against ENDS products sold in a specific category of retail outlets. Although the March 2019 Draft Guidance proposed to focus its enforcement priorities for flavored ENDS products on how the product was sold (regardless of the type of retail establishment), after considering the comments, the public health threats, and new evidence, FDA determined that focusing on how the product was sold would not be sufficient to address youth use of these products. Given the urgent need to address the dramatic rise in youth use, this Final Guidance prioritizes enforcement with respect to any flavored, cartridge-based ENDS products (other than a tobacco- and menthol-flavored ENDS product) without regard to the location or method of sale. With respect to tobacco-, menthol-, and non-flavored ENDS products as well as flavored cartridge-based ENDS products, the Final Guidance states that FDA does not intend to prioritize enforcement where manufacturers have

	taken adequate measures to prevent youth access. These types of measures generally are among those that manufacturers have informed FDA that they are capable of implementing for ENDS products and none involve a specific category of retail outlet.
Lack of clarity for retail locations • Should retail locations have age verification at their door or a separate room for the sale of any ENDS products? • Can retail locations employ less burdensome alternatives? • Concern that the policy could make traditional cigarette products more easily accessible than ENDS products. • Need clarity on how manufacturers or wholesalers can document adequate measures to prevent youth access. • How are retail outlets supposed to balance space constraints with youth access concerns? • FDA should give existing enforcement mechanisms the chance to succeed or focus on enforcing existing mechanisms before instituting new policy.	FDA has provided additional details regarding factors that it intends to consider in assessing whether a manufacturer is taking adequate measures to prevent youth access. For example, the Final Guidance lists several different types of programs to monitor compliance with age-verification and sales restrictions, all of which are programs that some manufacturers have stated they are capable of implementing for ENDS products. Unlike the Draft Guidance, it does not include, as a factor for prioritization, whether the product is sold by retailers in a location where minors are able to enter at any time. The March 2019 Draft Guidance proposed to focus its enforcement priorities of flavored ENDS products on how the product was sold (regardless of the type of retail establishment). After considering the comments, the public health threats, and new evidence, FDA determined that, to address youth use of these products, this Final Guidance should prioritize enforcement with respect to any flavored, cartridge-based ENDS products (other than a tobacco- and menthol-flavored ENDS product) without regard to the location or method of sale. The alarming data on the increase in youth use of ENDS products shows that the FDA's enforcement efforts to date did not adequately address this problem.
Enforcement priorities would effectively ban many retailers from selling ENDS products while allowing sales from vape shops and online retailers. • Concerns that many retailers will be forced to close. • Concerns that this will just cause retailers to shift unauthorized products to vape shops and other stores.	This Final Guidance prioritizes enforcement with respect to any flavored, cartridge-based ENDS products (other than a tobacco- and menthol-flavored product) without regard to the location or method of sale. In addition, the Final Guidance explains that FDA intends to prioritize enforcement for lack of a marketing authorization for tobacco-, menthol-, and non-flavored ENDS products and for non-

• Concerns about the rise in youth use of open tank systems and sourcing of e-vapor products at vape shops, as indicated by an analysis of Wave 2 (2014-2015) to Wave 3 (2015-2016) of results from the PATH study.	cartridge-based flavored ENDS products where the manufacturer is not taking adequate measures to prevent youth access to ENDS products. For example, the Final Guidance lists several different types of programs to foster compliance with age-verification and sales restrictions, all of which are programs that some manufacturers have stated they are capable of implementing for ENDS products. Finally, FDA notes that there has been a dramatic rise in youth use of cartridge-based ENDS products since Wave 3 of the PATH study was completed in 2016, as demonstrated by results from the NYTS in 2018 and 2019. These recent data inform FDA's serious public health concerns regarding the sale of certain flavored, cartridge-based products without premarket authorization. Moreover, although this Final Guidance should have minimal impact on those vape shops that primarily sell non-cartridge ENDS products and ensure that purchasers are of the requisite age and are not purchasing for resale (*e.g.*, are not purchasing in large quantities), should evidence indicate to the contrary, the Agency will take appropriate action.
Stricter enforcement of current age verifications rules would be an effective enforcement strategy. • Lax enforcement is a primary driver of youth ENDS use. • FDA should increase penalties to retailers who violate current regulations and sell to minors. • Age verification should be as strong as it is for alcohol. • There is a need for stricter age verification for online sales of ENDS products.	As described in the Final Guidance, FDA vigorously enforces the age verification requirements in its compliance check program. FDA has been focusing enforcement efforts on age verification as a strategy to address youth use of tobacco products, and FDA continues to enforce age restrictions. However, FDA believes that age verification alone is not sufficient to address this issue, given the most recent data that youth use of ENDS products continues to increase. FDA determined that focusing on how the product was sold would not be sufficient to address youth use of these products given the many sources of products available for youth access. The reality is that youth have continued access to ENDS products in the face of legal prohibitions and even after voluntary actions by some manufacturers. FDA believes that the policy expressed in the

	Final Guidance is a more appropriate means to combat youth use of, and access to, these products.
Many companies already comply with age verification requirements. • Policies that encourage additional measures would harm law-abiding retailers.	The Final Guidance does not require additional age verification measures. Instead, it states that FDA intends to prioritize enforcement for lack of a marketing authorization for tobacco-, menthol-, and non-flavored ENDS products as well as non-cartridge-based flavored ENDS products where the manufacturer is not taking adequate measures to prevent youth access to ENDS products.
Online sales of ENDS products should be banned.	This suggested sales restriction is outside of the scope of this guidance, which concerns enforcement of the premarket authorization requirements. At this time, FDA is finalizing this Guidance to address its concerns regarding youth use of ENDS products. The guidance prioritizes enforcement with respect to flavored, cartridge-based ENDS products because data shows that flavors are the primary driver in youth experimentation with, and continued use of, ENDS products, and that youth overwhelmingly use cartridge-based ENDS products. These priorities apply whether the products are sold online or in brick-and-mortar stores. However, the Agency will continue to monitor this issue.
Lack of clarity on what quantity limits for online sales would entail.	Given the data that many youth obtain their ENDS products from friends or sources in their social networks, FDA believes that quantity limits are one measure that a manufacturer could adopt to prevent individuals from purchasing large quantities of ENDS products to then distribute to minors on a secondary market. FDA's enforcement decisions will be made on a case-by-case basis and depend on many factors, but FDA intends to consider whether a manufacturer limits the quantity of ENDS products that a customer may purchase within a given period of time as a factor in assessing whether a manufacturer is taking adequate measures to prevent youth access. There is wide variation in these types of ENDS products and, based on some of the comments FDA received and the responses to the Agency's

	September 12, 2018 letters, FDA believes individual manufacturers are best positioned to know how to set purchase limits for their specific products. Therefore, FDA does not believe that further detail is warranted regarding this issue.
Age to purchase ENDS products should be increased to 21.	On December 20, 2019, the President signed into law legislation that raised the federal minimum age of sale of tobacco products from 18 to 21 years. FDA views this as a major step in protecting the next generation of youth from becoming addicted to ENDS and other tobacco products. FDA believes, however, that this change alone is not sufficient to address the epidemic use of ENDS by youth, especially use of flavored, cartridge-based products (except for tobacco- or menthol-flavored products) that are easily concealed, produced on a large scale, and (in some cases) sold in bulk quantities that has helped enable resale through social or black market sources. As part of the premarket review process for these products, FDA intends to consider measures taken by manufacturers to control youth access to these products.
Purchasing from other adolescents is a major factor driving ENDS usage in youth populations. • FDA should increase penalties for individuals who provide products to youth. • This type of behavior should be the responsibility of parents, not the government. • Only specialty vape stores should be permitted to sell ENDS. • Data from CDC's 2017 Youth Risk Behavior Surveillance System (YRBSS) found that 86.4% of youth who used ENDS did not purchase them at a retail store. • Youth will find ways to purchase restricted flavored products and increased regulations will be ineffective.	FDA agrees that social sources remain a concern for ENDS and other tobacco products. Given the popularity of social sources, FDA believes that quantity limits could be effective in preventing individuals from purchasing large quantities of ENDS products to then distribute to minors on a secondary market. Accordingly, FDA intends to consider whether a manufacturer limits the quantity of ENDS products that a customer may purchase within a given period of time as a factor in assessing whether a manufacturer is taking adequate measures to prevent youth access.

Limits on retail or online sales would remove two of the top purchase options for adult ENDS product users.	The priorities in the Final Guidance are addressed to particular products, not retailers. FDA believes that the Final Guidance strikes an appropriate balance between preventing youth access to ENDS products and maintaining availability of potentially less harmful options for current adult smokers who have transitioned or wish to transition completely away from combusted tobacco products. FDA would consider measures taken by manufacturers to control youth access, not adult access, when determining whether to enforce the premarket authorities with respect to these products.
Does not provide adequate reasoning or specificity for manufacturers to understand what marketing actions would prompt enforcement actions.	FDA's decision to exercise its enforcement authorities with respect to particular products will be determined on a case-by-case basis, informed by the enforcement priorities described in this Final Guidance and any other relevant factors. The Final Guidance provides a number of examples of measures manufactures can take to help prevent youth access to their tobacco products. Such examples reflect information provided by manufacturers in response to the Agency's September 12, 2018 letters, including measures to address youth use that manufacturers can or have already taken to address youth access to ENDS products, as well as information provided in comments to the March 2019 Draft Guidance.
Modifications to ENDS Compliance Policy – flavored ENDS offered for sale after August 8, 2021, without the manufacturer submitting (and FDA receiving) a premarket application	
Comment	Response
Moving up the compliance review date would be harmful. • Has the potential to impact adults using ENDS products for smoking cessation purposes. • Will harm businesses that have already planned for the initial date. • Will exacerbate an already burdensome premarket review process. • Will be difficult for small businesses to submit complete applications by August 8, 2021.	The Tobacco Control Act provides that new tobacco products may not be legally marketed without premarket authorization. Accordingly, all deemed new tobacco products on the market without authorization are illegally marketed products. As discussed in the Final Guidance, industry had notice that FDA would revisit its compliance policy if necessary. The Final Guidance announces that FDA intends to prioritize for enforcement ENDS products for which a premarket application has not been submitted by May 12, 2020. FDA understands the concerns expressed by these commenters but believes that it

	is appropriate for ENDS products to undergo premarket review on a shorter timeframe given the rise in youth use, in addition to other new and continuing public health and safety concerns, such as the outbreak of pulmonary injuries and battery hazards.
Leaving products on the market for this long is problematic. • Date is still too far away and will allow harmful products to remain on the market. • Deadline means longer time for products on the market to continue to make unsubstantiated claims without scientific review. • Leaving products on the market is problematic due to lack of evidence justifying later premarket review.	FDA agrees with these commenters that the proposed August 8, 2021, date would allow products that may be harmful to remain on the market too long, would allow products to market unsubstantiated claims without scientific review, and that the data before the agency does not justify later premarket review. The Final Guidance discusses the date for premarket application submission and the importance of earlier submission of applications to allow for FDA to better evaluate whether these products meet applicable premarket standards, such as whether the products are appropriate for the protection of the public health, considering the risks and benefits to the population as a whole, including users and nonusers of the tobacco product.
Lack of clarity around date for submission of premarket review applications • FDA should articulate the status of submitted premarket applications and provide manufacturers opportunity to amend applications in light of changing deadlines. • Still unclear what information must be included in a PMTA and/or SE report	The Final Guidance discusses dates for submission of applications for premarket review and provides links to application submission information, including where to view marketing orders and accompanying documentation, available at FDA.gov. FDA has provided guidance and information to industry on the premarket pathways through publishing guidances and marketing orders, as well as posting information via webinars and public workshops.[107]

[107] For more information on premarket tobacco product applications please see Premarket Tobacco Product Applications for [ENDS], Guidance for Industry (June 2019), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends; Applications for Premarket Review of New Tobacco Products (updated June 2019) available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-premarket-review-new-tobacco-products. For more information on CTP's other published regulations and guidances, please see https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance; for more information on FDA CTP webinars, please see https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars; for information on marketing orders and accompanying documentation, please see https://www.fda.gov/tobacco-products/compliance-enforcement-training.

Modifications to ENDS Compliance Policy – targeted to minors or likely to promote use of ENDS product by minors	
Comment	Response
FDA should use its authority to require ENDS manufacturers to stop running ads with unsubstantiated claims about smoking cessation and modified risk claims.	This is outside of the scope of the Final ENDS guidance, which addresses premarket review requirements for ENDS products. FDA closely monitors retailer, manufacturer, importer, and distributor compliance with Federal tobacco laws and regulations and takes corrective action when violations occur. When enforcing FDA's tobacco product authorities, the Agency generally issues a warning letter the first time a compliance check reveals a violation of federal tobacco laws and regulations, including when a manufacturer sells or distributes a product as a modified risk tobacco product without an FDA order in effect. Failure to promptly and adequately correct all violations and ensure compliance with all applicable laws and regulations may lead to enforcement actions, including civil money penalties, seizure, and/or injunction. To the extent that manufacturers are marketing their products for therapeutic purposes, they are subject to FDA's medical product authorities.
Lack of clarity – it is unclear what ENDS products manufacturers (and other parties that engage in ENDS marketing activities) and retailers can do to avoid concerning marketing activities. • Would like to know what specific steps they can take to ensure their marketing reaches adults rather than minors. • Need clarity on what the agency considers targeting or promoting to minors.	FDA believes the level of detail and examples in the Final Guidance provide sufficient clarity.
FDA should ensure social media platforms are not used as advertising platforms for ENDS products, including monitoring videos that promote ENDS products and limiting the reach of social media influencers who promote products.	To the extent this comment is about the advertising of ENDS products generally, it is outside the scope of the policy. To the extent this comment is about advertising of ENDS products that are targeted to minors or likely to promote use of ENDS by minors, FDA believes the Final Guidance addresses this by indicating that such products will be an enforcement priority.

A number of ENDS products are designed to be small and discreet, thus promoting ENDS use in minors.	The Final Guidance discusses the Agency's intent to prioritize its enforcement for products that are targeted to minors or likely to promote use of ENDS by minors. One example of such products includes products marketed directly to minors by promoting ease of concealment.
FDA should support stakeholder partnerships to develop common approach and standards in preventing youth access.	FDA CTP's Office of Stakeholder Relations regularly connects with stakeholders. Stakeholders also have access to the ombudsman as well.
Flavored Cigars	
Comment	Response
Enforcing the premarket requirements against flavored cigars would limit adults' freedom to choose their preferred products.	The Final Guidance does not include a policy to prioritize flavored cigars for enforcement. Instead, as described in the Final Guidance, flavored cigars are treated like all other deemed products that are not ENDS. Flavored cigars may seek premarket authorization from FDA. Manufacturers of flavored cigars, and of other deemed new tobacco products, will be required to submit marketing applications for those products by May 12, 2020, consistent with the U.S. District Court for the District of Maryland's order, as described in the Guidance.
Eliminating flavored cigars would result in the creation of a black market.	The Final Guidance does not include a policy to prioritize flavored cigars for enforcement. In addition, we do not think development of a black market is likely given that there are a number of "grandfathered" flavored cigars that are lawfully marketed and would remain available to consumers regardless of FDA's enforcement of premarket authorities.
FDA's assertion of product migration of youth is an unfounded hypothesis. • Concerns that FDA mischaracterizes research and does not cite contrary government findings (citing to CDC reports and PATH data) • FDA's data on this topic limited to two studies that only recently became available and has not been vetted • There are limitations to the Wave 1-3 PATH data that FDA cites in support	The Final Guidance does not include a policy to prioritize flavored cigars for enforcement.

• FDA relies on 2018 NYTS data and incorrectly speculates that youth could migrate to flavored cigars • CDC MMWR data and PATH data contradict suggestions that youth usage of cigars is on the rise • Data show decreasing importance of flavors to first time cigar users	
Only allowing 30 days after guidance is finalized would result in a de facto ban on flavored cigars. • Not enough time for manufacturers to submit SE reports. • May not be enough time for retailers to sell off inventory/FDA should include an additional sell off period of time to the compliance guidance. • Should be able to remain on the market until FDA has reviewed and made a determination on the premarket review application.	The Final Guidance does not include a policy to prioritize flavored cigars for enforcement. In addition, we note that there are a number of "grandfathered" flavored cigars that are lawfully marketed that would remain available to consumers regardless of FDA's enforcement of premarket authorities.
Guidance should address grandfathered flavored cigar products as well.	The Draft and Final Guidance are about enforcement against products that lack required premarket authorization. Grandfathered tobacco products, which do not require premarket authorization, are outside the scope of the policy.
Lack of clarity • Lack of a definition of flavored cigars will lead to confusion and leave retailers misinformed about what constitutes a flavored cigar. • Lack of definition of characterizing flavor.	The Final Guidance no longer discusses prioritizing enforcement for flavored cigars.
FDA should pursue the flavored cigar enforcement policy addressed in the Draft Guidance.	At this time, FDA has decided to focus this Final Guidance on ENDS products, given the recent surge in youth use and additional considerations such as battery explosions and vaping-related illnesses. Nevertheless, FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data. FDA will take appropriate action regarding tobacco products that are marketed without premarket authorization, including cigars, in accordance with the court's order in *American*

	Academy of Pediatrics. FDA also has stated its intention to issue a flavored cigar rule.
Compliance Policy for Other Deemed Products	
Comment	Response
FDA should modify compliance policy for other deemed products. • Data on waterpipe tobacco use demonstrates increase in youth use.	As discussed in the Final Guidance, consistent with the U.S. District Court for the District of Maryland's order, FDA intends to enforce premarket requirements for these products after May 12, 2020.
FDA should not modify compliance policy for other deemed products.	As discussed in the Final Guidance, consistent with the U.S. District Court for the District of Maryland's order, FDA intends to enforce premarket requirements for these products after May 12, 2020.
FDA should focus its efforts on menthol cigarettes.	The Final Guidance describes FDA's policy on enforcing premarket requirements for products subject to the deeming rule. Menthol cigarettes are outside the scope of this policy.

Exhibit 10

Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule

Guidance for Industry (Revised)*

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with FDA-2017- D-2834.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877- CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

August 2017

* This is a revision to the first edition of this guidance, which issued in May 2017.

Table of Contents

Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule

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Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document is intended to assist any person who manufactures, packages, sells, offers to sell, distributes, or imports for sale and distribution within the United States newly regulated tobacco products, roll-your-own tobacco, and cigarette tobacco. This guidance document discusses:[1]

- FDA's extension of future compliance deadlines for certain provisions under the May 2016 final Deeming rule.[2]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance was prepared by the Office of Regulations and the Office of Compliance and Enforcement in the Center for Tobacco Products at FDA.

[2] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016).

II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (section 901(b) of the FD&C Act).

In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of a tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority. This included electronic nicotine delivery systems (ENDS), cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28976).

Chapter IX of the FD&C Act now applies to newly regulated products, including sections 904(a)(1) and (4) (ingredient listing and health document submissions), 903(a)(4) and 903(a)(8) (labeling requirements), 904(c)(1) (timing of submissions), 905(b), (c), (d), and (h) (establishment registration), 905(i)(1) (product listing), 907(a)(1)(B) (additional special rules), 911 (modified risk claims), 904(a)(3) and 915 (harmful and potentially harmful constituent reporting), 920 (labeling, recordkeeping, and records inspection), and 905 and 910 (premarket review requirements). The final rule also included several requirements that apply to a subgroup of products referred to "covered tobacco products."[3]

In May 2017, FDA published the first edition of this guidance document, under which it provided a three-month extension of all future compliance deadlines for requirements under the final deeming rule. The May 2017 guidance applied to all categories of newly regulated products, including ENDS (e.g., e-cigarettes and e-cigars), hookah, pipe tobacco, and cigars, as well as the addictiveness warning requirement for RYO and cigarette tobacco. The guidance noted that the three-month extension did not apply to requirements under the final deeming rule where compliance deadlines already had passed, such as mandatory age and photo-ID checks to prevent illegal sales to minors. It explained that FDA would continue to enforce such requirements.

[3] The final deeming rule defines covered tobacco product to include any tobacco product deemed to be subject to Chapter IX of the FD&C Act under 21 C.F.R. 1100.2, but "excludes any component or part that is not made or derived from tobacco" (21 C.F.R. § 1140.3).

III. DISCUSSION

A. FDA's Extension of Certain Future Compliance Deadlines Related to the Final Deeming Rule

FDA is providing a further extension of certain future compliance deadlines for requirements under the final deeming rule. This further extension applies only to compliance deadlines relating to premarket review requirements, specifically for substantial equivalence exemption requests (SE EX requests), substantial equivalence reports (SE reports), and premarket tobacco product applications (PMTAs). No compliance deadlines relating to other provisions in the final deeming rule are being further extended, either those that have already passed and are being enforced, or those scheduled for a future date that were extended in the May 2017 guidance.

The further extension of premarket review compliance deadlines covered by this guidance applies to all categories of newly regulated products that were on the market on August 8, 2016, including ENDS (e.g. e-cigarettes and e-cigars), hookah, pipe tobacco, and cigars. The compliance dates are being extended from November 8, 2017 (SE EX requests), May 8, 2018 (SE reports), and November 8, 2018 (PMTAs) to August 8, 2021 (SE EX requests, SE reports, and PMTAs for newly regulated combustible tobacco products, such as most cigars, pipe tobacco and hookah tobacco) and August 8, 2022 (SE EX requests, SE reports, and PMTAs for newly regulated noncombustible tobacco products, such as most ENDS or e-cigarettes). These new compliance dates are reflected in the chart in Section III.B., along with the compliance dates from the May 2017 guidance that are not being further extended.

The preamble to the May 10, 2016, final deeming rule explained that FDA was providing two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization. It explained that under the latter compliance period:

> Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period.

81 Fed. Reg. 29,011 (May 10, 2016). The preamble further explained that this compliance policy did not apply to any new tobacco product that was not on the market on August 8, 2016. *Id*. FDA is revising the compliance policy relating to the period after FDA receipt of SE EX requests, SE reports, and PMTAs for newly regulated products that were on the market on August 8, 2016. Under this new compliance policy, there will be a continued compliance period pending review of those applications (SE EX requests, SE reports, and PMTAs). This compliance period will continue until the agency renders a decision on an application (i.e., issuance of: a Marketing Order; a No Marketing Order; a Refuse to File; or Refuse to Accept) or the application is withdrawn. The chart in Section III.B has been revised from the first edition of this guidance, issued in May 2017, to reflect this revised compliance policy.

For purposes of this guidance, FDA is using "future compliance deadlines" to refer to dates in the future on which it intends to begin enforcement of certain requirements under the deeming rule. Such dates include both (1) the effective date a particular requirement will become effective as a matter of law (e.g., the effective date for the health warning requirements in 21 C.F.R. part 1143) or (2) a compliance date that FDA has set as a matter of enforcement discretion, stating that it does not intend to enforce a particular requirement that is already in effect for a period of time in order to give industry more time to comply (e.g., compliance dates for various provisions of the FD&C Act set forth in the preamble to the final deeming rule, see 81 FR 29006).

This guidance revises and updates the first edition of this guidance, issued in May 2017. As with the May 2017 guidance, the compliance dates announced in this guidance supersede the compliance dates included in any other guidance issued prior to this guidance.

B. Compliance Dates

The compliance dates for requirements under the final deeming rule are detailed in the following chart. Requirements under the final deeming rule where compliance deadlines have already passed are not affected by this guidance and are not listed on the chart.

Required Warning Statements

Provision	Products Affected	Requirement and Compliance Date Under This Guidance
Product packages and ads must contain the addictiveness warning statement (21 C.F.R. § 1143.3(a) and (b)) • "WARNING: This product contains nicotine. Nicotine is an addictive chemical." • The warning must follow size and format requirements	Cigarette tobacco, roll-your-own tobacco, and covered tobacco products (other than cigars and those covered tobacco products that do not contain nicotine)	Manufacturers, importers, distributors, and retailers who direct their own advertising: Advertisements must bear the addictiveness warning August 10, 2018 Manufacturers cannot manufacture products with non-compliant packages August 10, 2018 Manufacturers cannot distribute such products irrespective of the date of manufacture September 11, 2018 Retailers cannot offer for sale, sell, distribute, or import products with non-compliant packages unless the retailer falls within the retailer safe harbor[4] August 10, 2018
Product packages and ads of covered tobacco products <u>that do not contain nicotine</u> may bear an alternative warning statement: • "This product is made from tobacco." • Manufacturers must submit to FDA a self-certification • For more information, visit FDA.gov and search for "extending authorities"	Covered tobacco products that do not contain nicotine	Manufacturers, importers, distributors, and retailers who direct their own advertising: Advertisements must bear the alternative warning August 10, 2018 Manufacturers cannot manufacture products with non-compliant packages August 10, 2018 Manufacturers cannot distribute such products irrespective of the date of manufacture September 11, 2018

[4] A retailer of any cigarette tobacco, roll-your-own tobacco, or covered tobacco products (other than cigars) will not be in violation of this section for packaging that: (i) Contains a health warning; (ii) Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable; and (iii) Is not altered by the retailer in a way that is material to the requirements of this section. 21 C.F.R §1143(a)(3)(ii).

		Retailers cannot offer for sale, sell, distribute, or import products with non- compliant packages unless the retailer falls within the safe harbor[5] August 10, 2018
Rotational cigar warning statements on product packages and ads (21 C.F.R. § 1143.5) • Cigar product packages and ads must contain warnings that follow size format, rotational, and distribution requirements • For more information, visit FDA.gov and search for "extending authorities"	Cigars	Manufacturers, importers, distributors, and retailers who direct their own advertising: Advertisements must bear one of the required warnings August 10, 2018 Manufacturers cannot manufacture products with non-compliant packages August 10, 2018 Manufacturers cannot distribute such products beginning irrespective of the date of manufacture September 11, 2018 Retailers cannot offer for sale, sell, distribute, or import products with non-compliant packages unless the retailer falls within the safe harbor[6] August 10, 2018

[5] A retailer of any covered tobacco products that do not contain nicotine and may bear the alternative warning statement will not be in violation of this section for packaging that: (i) Contains a health warning; (ii) Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable; and (iii) Is not altered by the retailer in a way that is material to the requirements of this section.

[6] A cigar retailer will not be in violation of this section for packaging that: (i) Contains a health warning; (ii) Is supplied to the retailer by the tobacco product manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable; and (iii) Is not altered by the retailer in a way that is material to the requirements of this section.

Point-of-sale warning statement requirement for cigars sold individually without packaging (21 C.F.R. § 1143.5(a)(3)) • Specific placement and formatting requirements • Sign must bear all six required warnings • For more information, visit FDA.gov and search for "extending authorities"	Cigars sold individually without packaging	August 10, 2018
Cigar warning plans on how warnings will be randomly displayed and distributed on packages and rotated on advertisements must be submitted to and approved by FDA (21 C.F.R. § 1143.5(c)(1)) For more information, visit FDA.gov and search for "extending authorities"	Cigars	August 10, 2017

Premarket Review Requirements

Compliance Period	Products Affected	Compliance Date Under this Guidance
Compliance period for manufacturers to submit a substantial equivalence exemption request (§910 of the FD&C Act) For more information, visit FDA.gov and search for "substantial equivalence"	New,[7] newly deemed finished tobacco products[8 9] that were on the market as of August 8, 2016	August 8, 2021 (combustible tobacco products) August 8, 2022 (noncombustible tobacco products)
Compliance period for manufacturers to submit a substantial equivalence report (§910 of the FD&C Act) For more information, visit FDA.gov and search for "substantial equivalence"	New, newly deemed finished tobacco products[10] that were on the market as of August 8, 2016	August 8, 2021 (combustible tobacco products) August 8, 2022 (noncombustible tobacco products)
Compliance period for manufacturers to submit a premarket tobacco product application (PMTA) (§905 of the FD&C Act) For more information, visit FDA.gov and search for "premarket tobacco product applications"	New, newly deemed finished tobacco products[11] that were on the market as of August 8, 2016	August 8, 2021 (combustible tobacco products) August 8, 2022 (noncombustible tobacco products)

[7] A "new tobacco product" is any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. §910(a)(1) of the FD&C Act.

[8] FDA has defined "finished tobacco product" as a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits).

[9] Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the premarket authorization requirements to newly regulated finished tobacco products at this time.

[10] Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the premarket authorization requirements to newly regulated finished tobacco products at this time.

[11] Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the premarket authorization requirements to newly regulated finished tobacco products at this time.

Other Provisions

Provision	Products Affected	Compliance Date Under this Guidance
Registration of establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product and product listings (§905(b), (c), (d), (h), and (i)(1) of the FD&C Act)	Newly deemed finished tobacco products[12]	For entities engaged in the manufacture, preparation, compounding, or processing of tobacco products in the United States prior to August 8, 2016, and continuing operations after August 8, 2016: September 30, 2017 For entities first engaging in the manufacture, preparation, compounding, or processing of tobacco products in the United States on or after August 8, 2016: **Immediately upon first engaging in the manufacturing of a tobacco product**
Ingredient listing (§904(a)(1) of the FD&C Act) For more information, visit FDA.gov and search for "tobacco ingredients"	Newly deemed finished tobacco products[13]	For products on the market on August 8, 2016: **November 8, 2017,** or **May 8, 2018** for small-scale tobacco product manufacturers[14] For products entering the market after **August 8, 2016:** 90 days prior to marketing

[12] Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the registration and product listing requirements to newly regulated finished tobacco products at this time.

[13] Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the ingredient listing requirements to newly regulated finished tobacco products at this time.

[14] FDA considers "small-scale tobacco product manufacturers" to be a manufacturer of any regulated tobacco product with 150 employees or fewer and annual total revenues of $5,000,000 or less.

Other Provisions (Continued)

Provision	Products Affected	Compliance Date Under this Guidance
Harmful and potentially harmful constituents (HPHCs) (§904 and 915 of the FD&C Act) For more information, visit FDA.gov and search for "HPHC"	Newly deemed finished tobacco products[15]	November 8, 2019 or For products entering the market after November 8, 2019: 90 days prior to marketing
Tobacco health documents (§904(a)(1) and (4) of the FD&C Act) For more information, visit FDA.gov and search for "tobacco health documents"	Newly deemed finished tobacco products[16]	November 8, 2017, for small-scale tobacco product manufacturers[17]
Prohibition on the introduction into interstate commerce of products that contain "light," "low," "mild," or other similar descriptors in the label, labeling, or advertising of such products without a modified risk tobacco product order in effect (§911 of the FD&C Act) For more information, visit FDA.gov and search for "modified risk"	All newly deemed tobacco products	Stop manufacturing: November 8, 2017 Stop distribution into interstate commerce: December 8, 2017
Tobacco products will be considered misbranded unless they bear a label containing the following information (§903(a)(2) of the FD&C Act): • The name and place of business • Quantity of the contents • Percentage of domestic and foreign-grown tobacco[18]	All newly deemed tobacco products in package form	August 10, 2018

[15] Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the HPHC reporting requirements to newly regulated finished tobacco products at this time.

[16] Note that while the deeming rule extends FDA's tobacco product authority to all tobacco products (except for accessories of newly deemed tobacco products), FDA intends to limit enforcement of the tobacco health document submission requirements to newly regulated finished tobacco products at this time.

[17] FDA considers "small-scale tobacco product manufacturers" to be a manufacturer of any regulated tobacco product with 150 employees or fewer and annual total revenues of $5,000,000 or less. The compliance deadline for submission of tobacco health documents for entities other than small-scale tobacco product manufacturers has already passed (February 8, 2017) and is not affected by the extension announced in this guidance.

18 FDA issued a Draft Guidance titled "Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Food, Drug, and Cosmetic Act Requirements to Vape Shops," which included a proposed compliance policy relating this requirement (pp. 5-6). This compliance policy would apply to all tobacco products.

·The statement: "Sale only allowed in the United States" on labels, packaging, and shipping containers of tobacco products		
All required label and labeling statements must be prominent and in such terms that render it likely to be read and understood (§903(a)(3) of the FD&C Act)	All newly deemed tobacco products	November 8, 2017

DOCUMENT HISTORY

May 2017 – First edition of guidance issued.

August 2017 – *Three-Month Extension of Certain Compliance Deadlines Related to the Final Deeming Rule* is revised to reflect changes to premarket review compliance policy related to "deemed" tobacco products. Specific revisions include the following:

- Title – Removal of "Three-Month" to reflect the inclusion of extended compliance deadlines for premarket review policy.
- Section II – Added explanation of extension of compliance policies included in May 2017 first edition of guidance.
- Section III.A – Added explanation of previous premarket review compliance policy and summary of revised premarket review compliance policy for deemed tobacco products.
- Section III.B – Updated chart to include revised premarket review compliance policy, and third column revised from "new compliance date" to "compliance date under this guidance" to provide additional clarity.

Exhibit 11

Determination that a Public Health Emergency Exists

As a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV), on this date and after consultation with public health officials as necessary, I, Alex M. Azar II, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby determine that a public health emergency exists and has existed since January 27, 2020, nationwide.

01/31/2020	/s/
Date	Alex M. Azar II

More Emergency and Response Information

- Declarations of a Public Health Emergency
- Public Health Emergency Determinations to Support an Emergency Use Authorization
- Section 1135 Waivers
- Emergency Use Authorizations

This page last reviewed: January 31, 2020

Exhibit 12

Presidential Documents

Proclamation 9994 of March 13, 2020

Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak

By the President of the United States of America

A Proclamation

In December 2019, a novel (new) coronavirus known as SARS–CoV–2 (''the virus'') was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID–19 that has now spread globally. The Secretary of Health and Human Services (HHS) declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID–19. I have taken sweeping action to control the spread of the virus in the United States, including by suspending entry of foreign nationals seeking entry who had been physically present within the prior 14 days in certain jurisdictions where COVID–19 outbreaks have occurred, including the People's Republic of China, the Islamic Republic of Iran, and the Schengen Area of Europe. The Federal Government, along with State and local governments, has taken preventive and proactive measures to slow the spread of the virus and treat those affected, including by instituting Federal quarantines for individuals evacuated from foreign nations, issuing a declaration pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d), and releasing policies to accelerate the acquisition of personal protective equipment and streamline bringing new diagnostic capabilities to laboratories. On March 11, 2020, the World Health Organization announced that the COVID–19 outbreak can be characterized as a pandemic, as the rates of infection continue to rise in many locations around the world and across the United States.

The spread of COVID–19 within our Nation's communities threatens to strain our Nation's healthcare systems. As of March 12, 2020, 1,645 people from 47 States have been infected with the virus that causes COVID–19. It is incumbent on hospitals and medical facilities throughout the country to assess their preparedness posture and be prepared to surge capacity and capability. Additional measures, however, are needed to successfully contain and combat the virus in the United States.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States, by the authority vested in me by the Constitution and the laws of the United States of America, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 *et seq.*) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b–5), do hereby find and proclaim that the COVID–19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020. Pursuant to this declaration, I direct as follows:

Section 1. *Emergency Authority.* The Secretary of HHS may exercise the authority under section 1135 of the SSA to temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children's Health Insurance programs and of the Health Insurance Portability and Accountability Act Privacy Rule throughout the duration of the public health emergency declared in response to the COVID–19 outbreak.

Sec. 2. *Certification and Notice*. In exercising this authority, the Secretary of HHS shall provide certification and advance written notice to the Congress as required by section 1135(d) of the SSA (42 U.S.C. 1320b–5(d)).

Sec. 3. *General Provisions*. (a) Nothing in this proclamation shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This proclamation shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This proclamation is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of March, in the year of our Lord two thousand twenty, and of the Independence of the United States of America the two hundred and forty-fourth.

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Filed 3–17–20; 8:45 am]
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Exhibit 13

Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

Situation Summary

This is a rapidly evolving situation and CDC will provide updated information and guidance as it becomes available.

Updated March 18, 2020

CDC is responding to a pandemic of respiratory disease spreading from person-to-person caused by a novel (new) coronavirus. The disease has been named "coronavirus disease 2019" (abbreviated "COVID-19"). This situation poses a serious public health risk. The federal government is working closely with state, local, tribal, and territorial partners, as well as public health partners, to respond to this situation. COVID-19 can cause mild to severe illness; most severe illness occurs in older adults.

Situation in U.S.

Different parts of the country are seeing different levels of COVID-19 activity. The United States nationally is currently in the initiation phases, but states where community spread is occurring are in the acceleration phase. The duration and severity of each phase can vary depending on the characteristics of the virus and the public health response.

- CDC and state and local public health laboratories are testing for the virus that causes COVID-19. View CDC's Public Health Laboratory Testing map.
- All 50 states have reported cases of COVID-19 to CDC.
- U.S. COVID-19 cases include:
  - Imported cases in travelers
  - Cases among close contacts of a known case
  - Community-acquired cases where the source of the infection is unknown.
- Three U.S. states are experiencing sustained community spread.
- View latest case counts, deaths, and a map of states with reported cases.

Confirmed COVID-19 Cases Global Map

CDC Recommends

- Everyone can do their part to help us respond to this emerging public health threat:
  - On March 16, the White House announced a program called "15 Days to Slow the Spread," which is a nationwide effort to slow the spread of COVID-19 through the implementation of social distancing at all levels of society.
  - Older people and people with severe chronic conditions should take special precautions because they are at higher risk of developing serious COVID-19 illness.
  - If you are a healthcare provider, use your judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Factors to consider in addition to clinical symptoms may include:
    - Does the patient have recent travel from an affected area?
    - Has the patient been in close contact with someone with COVID-19 or with patients with pneumonia of unknown cause?
    - Does the patient reside in an area where there has been community spread of COVID-19?
  - If you are a healthcare provider or a public health responder caring for a COVID-19 patient, please take care of yourself and follow recommended infection control procedures.
  - If you are a close contact of someone with COVID-19 and develop symptoms of COVID-19, call your healthcare provider and tell them about your symptoms and your exposure. They will decide whether you need to be tested. Keep in mind that there is no treatment for COVID-19 and people who are mildly ill are able to isolate at home.
  - If you are a resident in a community where there is ongoing spread of COVID-19 and you develop COVID-19 symptoms, call your healthcare provider and tell them about your symptoms. They will decide whether you need to be tested. Keep in mind that there is no treatment for COVID-19 and people who are mildly ill are able to isolate at home.
- For people who are ill with COVID-19, but are not sick enough to be hospitalized, please follow CDC guidance on how to reduce the risk of spreading your illness to others. People who are mildly ill with COVID-19 are able to isolate at home during their illness.
- If you have been in China or another affected area or have been exposed to someone sick with COVID-19 in the last 14 days, you will face some limitations on your movement and activity. Please follow instructions during this time. Your cooperation is integral to the ongoing public health response to try to slow spread of this virus.

COVID-19 Emergence

COVID-19 is caused by a coronavirus. Coronaviruses are a large family of viruses that are common in people and many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS-CoV, SARS-CoV, and now with this new virus (named SARS-CoV-2).

The SARS-CoV-2 virus is a betacoronavirus, like MERS-CoV and SARS-CoV. All three of these viruses have their origins in bats. The sequences from U.S. patients are similar to the one that China initially posted, suggesting a likely single, recent emergence of this virus from an animal reservoir.

Early on, many of the patients at the epicenter of the outbreak in Wuhan, Hubei Province, China had some link to a large seafood and live animal market, suggesting animal-to-person spread. Later, a growing number of patients reportedly did not have exposure to animal markets, indicating person-to-person spread. Person-to-person spread was subsequently

reported outside Hubei and in countries outside China, including in the United States. Some international destinations now have ongoing community spread with the virus that causes COVID-19, as do some parts of the United States. Community spread means some people have been infected and it is not known how or where they became exposed. Learn more about the spread of this newly emerged coronavirus.

Severity

The complete clinical picture with regard to COVID-19 is not fully known. Reported illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, a report out of China suggests serious illness occurs in 16% of cases. Older people and people of all ages with severe chronic medical conditions — like heart disease, lung disease and diabetes, for example — seem to be at higher risk of developing serious COVID-19 illness. A CDC Morbidity & Mortality Weekly Report that looked at severity of disease among COVID-19 cases in the United States by age group found that 80% of deaths were among adults 65 years and older with the highest percentage of severe outcomes occurring in people 85 years and older.

Learn more about the symptoms associated with COVID-19.

COVID-19 Pandemic

A pandemic is a global outbreak of disease. Pandemics happen when a new virus emerges to infect people and can spread between people sustainably. Because there is little to no pre-existing immunity against the new virus, it spreads worldwide.

The virus that causes COVID-19 is infecting people and spreading easily from person-to-person. Cases have been detected in most countries worldwide and community spread is being detected in a growing number of countries. On March 11, the COVID-19 outbreak was characterized as a pandemic by the WHO .

This is the first pandemic known to be caused by the emergence of a new coronavirus. In the past century, there have been four pandemics caused by the emergence of novel influenza viruses. As a result, most research and guidance around pandemics is specific to influenza, but the same premises can be applied to the current COVID-19 pandemic. Pandemics of respiratory disease follow a certain progression outlined in a "Pandemic Intervals Framework." Pandemics begin with an investigation phase, followed by recognition, initiation, and acceleration phases. The peak of illnesses occurs at the end of the acceleration phase, which is followed by a deceleration phase, during which there is a decrease in illnesses. Different countries can be in different phases of the pandemic at any point in time and different parts of the same country can also be in different phases of a pandemic.

There are ongoing investigations to learn more. This is a rapidly evolving situation and information will be updated as it becomes available.

Risk Assessment

Risk depends on characteristics of the virus, including how well it spreads between people; the severity of resulting illness; and the medical or other measures available to control the impact of the virus (for example, vaccines or medications that can treat the illness) and the relative success of these. In the absence of vaccine or treatment medications, nonpharmaceutical interventions become the most important response strategy. These are community interventions that can reduce the impact of disease.

The risk from COVID-19 to Americans can be broken down into risk of exposure versus risk of serious illness and death.

Risk of exposure:

- The immediate risk of being exposed to this virus is still low for most Americans, but as the outbreak expands, that risk will increase. Cases of COVID-19 and instances of community spread are being reported in a growing number of states.

- People in places where ongoing community spread of the virus that causes COVID-19 has been reported are at elevated risk of exposure, with the level of risk dependent on the location.
- Healthcare workers caring for patients with COVID-19 are at elevated risk of exposure.
- Close contacts of persons with COVID-19 also are at elevated risk of exposure.
- Travelers returning from affected international locations where community spread is occurring also are at elevated risk of exposure, with level of risk dependent on where they traveled.

Risk of Severe Illness:

Early information out of China, where COVID-19 first started, shows that some people are at higher risk of getting very sick from this illness. This includes:

- Older adults, with risk increasing by age.
- People who have serious chronic medical conditions like:
  - Heart disease
  - Diabetes
  - Lung disease

CDC has developed guidance to help in the risk assessment and management of people with potential exposures to COVID-19.

What May Happen

More cases of COVID-19 are likely to be identified in the United States in the coming days, including more instances of community spread. CDC expects that widespread transmission of COVID-19 in the United States will occur. In the coming months, most of the U.S. population will be exposed to this virus.

Widespread transmission of COVID-19 could translate into large numbers of people needing medical care at the same time. Schools, childcare centers, and workplaces, may experience more absenteeism. Mass gatherings may be sparsely attended or postponed. Public health and healthcare systems may become overloaded, with elevated rates of hospitalizations and deaths. Other critical infrastructure, such as law enforcement, emergency medical services, and sectors of the transportation industry may also be affected. Healthcare providers and hospitals may be overwhelmed. At this time, there is no vaccine to protect against COVID-19 and no medications approved to treat it. Nonpharmaceutical interventions will be the most important response strategy to try to delay the spread of the virus and reduce the impact of disease.

CDC Response

Global efforts at this time are focused concurrently on lessening the spread and impact of this virus. The federal government is working closely with state, local, tribal, and territorial partners, as well as public health partners, to respond to this public health threat.

Highlights of CDC's Response

- CDC established a COVID-19 Incident Management System on January 7, 2020. On January 21, CDC activated its Emergency Operations Center to better provide ongoing support to the COVID-19 response.
- The U.S. government has taken unprecedented steps with respect to **travel** in response to the growing public health threat posed by this new coronavirus:
  - Foreign nationals who have been in China, Iran, the United Kingdom, Ireland and any one of the 26 European countries in the Schengen Area within the past 14 days cannot enter the United States.
  - U.S. citizens, residents, and their immediate family members who have been any one of those countries within in the past 14 days can enter the United States, but they are subject to health monitoring and possible quarantine for up to 14 days.
  - People at higher risk of serious COVID-19 illness avoid cruise travel and non-essential air travel.

    - CDC has issued additional specific travel guidance related to COVID-19.
- CDC has issued clinical guidance, including:
    - Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19).
    - Infection Prevention and Control Recommendations for Patients, including guidance on the use of personal protective equipment (PPE) during a shortage.

- CDC also has issued guidance for other settings, including:
    - Preparing for COVID-19: Long-term Care Facilities, Nursing Homes
    - Discontinuation of Home Isolation for Persons with COVID-19

- CDC has deployed multidisciplinary teams to support state health departments in case identification, contact tracing, clinical management, and public communications.
- CDC has worked with federal partners to support the safe return of Americans overseas who have been affected by COVID-19.

This is a picture of CDC's laboratory test kit for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). CDC tests are provided to U.S. state and local public health laboratories, Department of Defense (DOD) laboratories and select international laboratories.

View Larger

- An important part of CDC's role during a public health emergency is to develop a test for the pathogen and equip state and local public health labs with testing capacity.
    - CDC developed an rRT-PCR test to diagnose COVID-19.
    - As of the evening of March 17, 89 state and local public health labs in 50 states, the District of Columbia, Guam, and Puerto Rico have successfully verified and are currently using CDC COVID-19 diagnostic tests.
    - Commercial manufacturers are now producing their own tests.
- CDC has grown the COVID-19 virus in cell culture, which is necessary for further studies, including for additional genetic characterization. The cell-grown virus was sent to NIH's BEI Resources Repository for use by the broad

scientific community.

- CDC also is developing a serology test for COVID-19.

Other Available Resources

The following resources are available with information on COVID-19

- World Health Organization, Coronavirus

Page last reviewed: March 18, 2020

Exhibit 14

THE PRESIDENT'S **CORONAVIRUS GUIDELINES** FOR AMERICA

15 DAYS TO SLOW THE SPREAD

Listen to and follow the directions of your **STATE AND LOCAL AUTHORITIES.**

IF YOU FEEL SICK, stay home. Do not go to work. Contact your medical provider.

IF YOUR CHILDREN ARE SICK, keep them at home. Do not send them to school. Contact your medical provider.

IF SOMEONE IN YOUR HOUSEHOLD HAS TESTED POSITIVE for the coronavirus, keep the entire household at home. Do not go to work. Do not go to school. Contact your medical provider.

IF YOU ARE AN OLDER PERSON, stay home and away from other people.

IF YOU ARE A PERSON WITH A SERIOUS UNDERLYING HEALTH CONDITION that can put you at increased risk (for example, a condition that impairs your lung or heart function or weakens your immune system), stay home and away from other people.

THE WHITE HOUSE

CDC

For more information, please visit
CORONAVIRUS.GOV

THE PRESIDENT'S **CORONAVIRUS GUIDELINES** FOR AMERICA

DO YOUR PART TO SLOW THE SPREAD OF THE CORONAVIRUS

Even if you are young, or otherwise healthy, you are at risk and your activities can increase the risk for others. It is critical that you do your part to slow the spread of the coronavirus.

Work or engage in schooling **FROM HOME** whenever possible.

IF YOU WORK IN A CRITICAL INFRASTRUCTURE INDUSTRY, as defined by the Department of Homeland Security, such as healthcare services and pharmaceutical and food supply, you have a special responsibility to maintain your normal work schedule. You and your employers should follow CDC guidance to protect your health at work.

AVOID SOCIAL GATHERINGS in groups of more than 10 people.

Avoid eating or drinking at bars, restaurants, and food courts — **USE DRIVE-THRU, PICKUP, OR DELIVERY OPTIONS.**

AVOID DISCRETIONARY TRAVEL, shopping trips, and social visits.

DO NOT VISIT nursing homes or retirement or long-term care facilities unless to provide critical assistance.

PRACTICE GOOD HYGIENE:

- *Wash your hands, especially after touching any frequently used item or surface.*
- *Avoid touching your face.*
- *Sneeze or cough into a tissue, or the inside of your elbow.*
- *Disinfect frequently used items and surfaces as much as possible.*

CORONAVIRUS.GOV

School operations can accelerate the spread of the coronavirus. Governors of states with evidence of community transmission should close schools in affected and surrounding areas. Governors should close schools in communities that are near areas of community transmission, even if those areas are in neighboring states. In addition, state and local officials should close schools where coronavirus has been identified in the population associated with the school. States and localities that close schools need to address childcare needs of critical responders, as well as the nutritional needs of children.

Older people are particularly at risk from the coronavirus. All states should follow Federal guidance and halt social visits to nursing homes and retirement and long-term care facilities.

In states with evidence of community transmission, bars, restaurants, food courts, gyms, and other indoor and outdoor venues where groups of people congregate should be closed.

Exhibit 15

Coronavirus (COVID-19) in California

COVID-19 is a new illness that can affect your lungs and airways. It's caused by a virus called coronavirus.

We're all in this together. We are working rapidly to keep our state healthy.

> **Stay home except for essential needs**
>
> Everyone is required to stay home except to get food, care for a relative or friend, get necessary health care, or go to an essential job. If you go out, keep at least 6 feet of distance.
>
> Learn more Aprenda más

Do:

- ✓ Stay home
- ✓ Wash hands with soap and water for at least 20 seconds
- ✓ Cover your cough or sneeze with a tissue
- ✓ Clean and disinfect frequently touched objects and surfaces
- ✓ If soap and water aren't available, use alcohol-based hand sanitizer

Don’t:

- × Shake hands
- × Touch your face
- × Go to the doctor if you aren’t sick
- × Stockpile masks or gloves

What you can do

- Know symptoms and risks
- Avoid gatherings and events
- Get testing and treatment
- Apply for unemployment
- Apply for disability benefits
- Apply for paid family leave
- Get help for small businesses

Latest numbers

As of **March 21, 2020** there are **1,224 positive cases** and **23 deaths** in California. Approximately **25,200 tests** had been conducted. This includes the latest numbers California has received from commercial and private labs. At least 12,528 results have been received and another 12,700+ are pending. See the California Department of Public Health (CDPH) for the latest data.

Latest news

March 20, 2020 at 8:56 PM

Governor Newsom Signs Order to Protect Public Health by Expanding Vote-by-Mail Options and Extending Deadlines for Presidential Primary Canvass

SACRAMENTO – Governor Gavin Newsom today issued an executive order to permit vote-by-mail procedures to be used in three upcoming special elections, protecting public health and safety during the COVID-19 outbreak. The o...

March 20, 2020 at 7:45 PM

Governor Newsom Deploys California National Guard to Help Distribute Food at Food Banks & Protect California's Most Vulnerable

Food banks are seeing a shortage in volunteers and experiencing greater need due to COVID-19 Governor calls for California food bank volunteers & launches partnership Neighbor-to-Neighbor campaign with Nextdoor.com ...

March 20, 2020 at 12:00 AM

State Officials Announce Latest COVID-19 Facts

The California Department of Public Health today announced the most recent statistics on COVID-19.

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Find services and information

🎓 Education

Many schools are closing campuses temporarily. Check your district for the latest.

💼 Employment and taxes

Find benefits for people affected by COVID-19. State tax deadlines have been extended.

💊 Health care

California is working to ensure everyone has healthcare coverage and access to testing.

Public places

Stay updated on recommendations to reduce further spread of coronavirus.

Get local information

Find and follow local public health authorities for the most updated guidance.

Your Actions Save Lives

We can all do our part to keep California healthy. Access our toolkit for videos and social media.

Department of Public Health

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Official California State Government Website

Exhibit 16

SPOTLIGHT PA | POWERED BY The Inquirer

Gov. Tom Wolf orders all Pennsylvania businesses that aren't 'life-sustaining' to close, will enforce order

by Angela Couloumbis of Spotlight PA, Updated: March 19, 2020

Spotlight PA is an independent, nonpartisan newsroom powered by The Philadelphia Inquirer in partnership with the Pittsburgh Post-Gazette and PennLive/Patriot-News. Sign up for our free weekly newsletter.

HARRISBURG — Gov. Tom Wolf on Thursday announced that all but "life-sustaining" businesses in Pennsylvania must shut down immediately as the state braces for exponential increases in the number of people sickened by the novel coronavirus.

» UPDATE (MARCH 20): Pa. business shutdown sows widespread confusion, impacts up to 3 million workers

Unlike earlier in the week — when Wolf urged nonessential businesses such as salons, gyms, theaters, and entertainment venues to voluntarily close — the latest order came with a stern warning: those out of compliance as of Saturday could face strict penalties.

Those businesses considered "life-sustaining" include grocery stores, gas stations, farms, and transit systems, according to the Wolf administration. The new order applies to the city of Philadelphia, which previously had been allowed to impose and enforce its own restrictions.

"To protect the health and safety of all Pennsylvanians, we need to take more aggressive mitigation actions," Wolf said in a statement. "This virus is an invisible danger that could be present everywhere. We need to act with the strength we use against any other severe threat. And, we need to act now before the illness spreads more widely."

The order takes effect immediately and will remain in place "until further notice."

» READ MORE: The full list of which Pa. businesses must close, which are considered 'life-sustaining,' as of March 20

Restaurants and bars across the state had already been required to stop dine-in services, and they are allowed to continue to offer takeout or delivery, the governor's office said. On Wednesday, state liquor control authorities said they, too, would begin enforcing the restrictions.

Now, the administration is cracking down across the board and will take action against any non-life-sustaining businesses out of compliance as of Saturday at 12:01 a.m. Asked which authorities would enforce the directive, a spokesperson for Wolf, Lyndsay Kensinger, said in an email, "Law enforcement has a range of potential actions when enforcing the governor's business closure order, such as notification that the closure order exists; warning to close; citation; and mandatory closure.

"Law enforcement will use appropriate discretion while ensuring that businesses are actively complying with the order," she said.

The governor's office issued a list Thursday of businesses that must close their physical operations. They include car dealers, lawn and garden stores, specialty food stores, and furniture stores. His order also applies to offices providing legal, accounting, architectural, and tax services.

"This is an extremely difficult situation for businesses," said Gene Barr, president of the Pennsylvania Chamber of Business and Industry. "It will cause real economic harm — it already has. But the governor had to make a tough choice."

There has been at least some initial confusion about the new directive. Ed Grose, executive director of the Greater Philadelphia Hotel Association, said Thursday that the governor's order initially sent hotels into a panic because it lists "traveler accommodations" as needing to close.

“Some of my hotels are housing doctors who are here” to help coronavirus patients, said Grose, adding that hotels were worried they would have to “throw people out on the street, including medical staff.”

He said the governor’s office has since said that it will clarify hotels can remain open.

“It caused total panic,” Grose said.

Republicans who control both chambers in the state legislature were critical of Wolf’s expanded order Thursday night, with Senate GOP leaders calling on Wolf to provide a process for employers to appeal his order.

House Republican leaders took it one step further, signaling they might sue.

“The sprawling and confusing list provided by the governor is provided with no explanation, and we will explore all avenues available to us to determine whether the action he’s taken is allowed within our state Constitution,” they said in a statement.

Earlier Thursday, the state education department announced the cancellation of all standardized tests, including the Keystone exams and the PSSAs, for the 2019-20 school year, joining several states that have already made such a move. The department is seeking waivers from the federal rules that require the tests.

The Wolf administration has been anxiously watching the march of the virus as it continues its unrelenting spread. The initial confirmed cases were at first largely clustered in Philadelphia and Montgomery Counties. Now, there are cases in more than 20 counties in the state.

Earlier in the day, Health Secretary Rachel Levine told reporters that the state had 52 new cases of COVID-19, bringing the statewide total to 185. On Wednesday, health officials announced the state’s first death from the virus, a 55-year-old man from Northampton County.

Since the start of the week, when the governor’s first statewide shutdown order went into effect, state officials have received 190,000 claims for unemployment benefits, a rapid and steep increase in applications that has the potential to overwhelm the system.

In an interview with reporters Thursday, Labor and Industry Secretary Jerry Oleksiak acknowledged that the unemployment compensation unit is operating with significantly fewer staffers because of the havoc created by the coronavirus. Many state government offices are shut down, with employees working from home.

But he and other labor officials noted that the lion’s share of applications are being filed electronically, and can be processed without the need for an employee to intervene if they do not contain errors.

“We began preparing for this a few weeks ago, as it became apparent this was not a drill,” Oleksiak said. “It was the real thing.”

In ordering the stricter shutdown Thursday, Wolf is drawing on powers that his administration said comes from the disaster emergency declaration he signed on March 6.

When Wolf declared the disaster emergency, he triggered a part of the state’s emergency management law that vastly expands a governor’s powers. They include everything from ordering mass evacuations to limiting or outright halting liquor and firearm sales.

Also among the new powers: controlling “ingress and egress to and from a disaster area, the movement of persons within the area, and the occupancy of premises therein.”

RELATED STORIES

- **FULL LIST: Which Pa. businesses must close, which are considered ‘life-sustaining’ under shutdown order**
- **Gov. Wolf’s shutdown order sows widespread confusion and panic. Up to 3 million workers affected**
- **SBA disaster loans now available for Pa. small businesses, nonprofits affected by coronavirus**

That is the section — coupled with other powers given to his administration from the the state's Disease Prevention and Control Law — that Wolf's advisers have said gives the governor the authority to shut down schools and order businesses to close.

TIPS

Do you have a tip about **how Pa.'s government is responding to the coronavirus**? Tell us.

Name

Email or phone number

What should we know?

Send message

Or see more secure ways to contact us

Or see more secure ways to contact us

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The Philadelphia Inquirer

THE CORONAVIRUS

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N.J.: Murphy says he'll "tighten the screws" to keep people apart.

TEST SITE: Home of the Phils has a parking lot covered with white tents.

KENNEY: City won't be "forceful" in asking people to restrict selves.

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DAILY NEWS

WEEKEND

MAR. 22, 2020

LINE OF DUTY

FRIENDS, LOVED ONES PUT THE CRISIS ON HOLD TO HONOR SLAIN HERO PAGE 3

CORONAVIRUS: THE LATEST

CONFUSION, PANIC ABOUND AMONG BUSINESSES PAGE 5

ANXIETY BREEDS PLENTY OF SCAM SCUM PAGE 7

MUSIC TO OUR FEARS: TUNES IN TOUGH TIMES PAGE 13

THE DAILY NEWS

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The Philadelphia Inquirer

Exhibit 17

MARCH 16, 2020 • CHARLIE MINATO • NEWS

ALL CIGAR FACTORIES IN HONDURAS CLOSED THIS WEEK DUE TO CORONAVIRUS

There will be no cigars rolled in Honduras this week due to concerns about the spread of coronavirus COVID-19.

Over the weekend, the Honduran government issued a ban on most workplaces and all gatherings of 50 or more people. There are a variety of exceptions to the outright ban on workplaces, including ones for essential services, hospitals, banks, hotels and restaurants that offer to-go services. As for the cigar industry, there are also exemptions for the agricultural industry as well as cargo and transport services meaning that some work in the Honduran cigar industry will likely continue, but the rolling of cigars has stopped for a week.

Rocky Patel, who makes cigars in Honduras with the Plasencia family, confirmed that the factories in Honduras were shut down. Representatives for Davidoff—which makes Camacho and Baccarat in Honduras—as well as Scandinavian Tobacco Group—parent of General Cigar Co.—also confirmed their operations were shut down due to the government decree.

“This is an unprecedented situation and we have to take whatever measures are recommended by the government,” said Christian Eiroa, founder of CLE, in a statement to *halfwheel.* “Despite our added procedures, our government has implemented more drastic measures which we are respecting effective immediately. I worry about the medicines available in Honduras and how all (of) these workers across the country will be able to live these next few weeks without income.”

Currently, Honduras has only six confirmed cases of COVID-19, but the government is concerned over the ability of the country’s health system to deal with a widespread outbreak. Effective this morning, the country closed its borders for travelers for at least seven days. The ban on travel will not affect cargo.

Honduras is the fourth-largest producer of premium cigars in the world. The other three—Cuba, the Dominican Republic and Nicaragua—are still in operation as of this morning.

Exhibit 18

Phone: 706-494-1143
Fax: 706-494-1893
website: www.ipcpr org
email: info@ipcpr.org

#4 Bradley Park Court Suite 2H
Columbus, Georgia 31904-3637

August 7, 2014

VIA ELECTRONIC FILING

Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2014-N-0189

Dear Sir or Madam:

The International Premium Cigar & Pipe Retailers Association ("IPCPR") submits these comments in response to the Food and Drug Administration's ("FDA's") proposed rule: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, As Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,142 (Apr. 25, 2014) (the "proposed deeming regulation"). IPCPR, based in Columbus, Georgia, is a not-for-profit trade group representing premium cigar and tobacco retail shops located throughout the United States and abroad. IPCPR, formerly the Retail Tobacco Dealers of America, was established in 1933. Its 1,700 retail members are small businesses, typically family-owned and operated. IPCPR members operate more than 2,000 retail stores, employ more than 8,000 people, and sell tobacco products, primarily premium cigars, in face-to-face sales, to adults. IPCPR also has a direct economic relationship with more than 350 manufacturers, distributors, and service providers, who employ 7,000 more people, who supply our retail members.

I. Comment on Whether All Cigars Should Be Subject to Deeming Provisions and Which Provisions of the Proposed Rule May Be Appropriate or Not Appropriate for Different Kinds of Cigars

IPCPR strongly opposes Option 1, and supports a slightly modified Option 2 taking into account our comments presented here. As explained in more detail in IPCPR's Citizen Petition (FDA-2011-P-0623), the scientific research demonstrates that the typical premium cigar consumer (1-2 cigars per day or less) is exposed to significantly lower health risks compared to cigarettes both quantitatively and qualitatively. Furthermore, as explained in the IPCPR Citizen Petition, premium cigars are not used to a significant extent by adolescents. Only Option 2 acknowledges these differences between premium cigars and all other tobacco products, and proposes to regulate premium cigars differently. Because premium cigars pose lower health risks than cigarettes and lack significant youth access, FDA's resources are better spent on regulating tobacco products that present more significant public health problems.

II. Comment on Whether the Proposed Definition of "Covered Cigar" is Appropriate to Capture Those Products That, Because of How They Are Used, May Have Less of a Public Health Impact Than Other Types of Cigars, Including Long Filler Tobacco Content, $10 Price Point, and Weight Restrictions as Proposed Elements

Under Option 2 of the proposed rule, FDA proposes to regulate "covered cigars." FDA then "carves out" from the regulations an exemption for certain cigars that have specific characteristics. It is this "carved out" class of cigars that FDA refers to as "premium cigars." The definition of a "covered cigar" is of critical importance to FDA, manufacturers, importers, distributors, retailers, and consumers. FDA investigators (and/or their state counterparts), as law enforcement agents, must be able to determine whether a cigar is a "covered cigar" subject to greater regulatory restrictions, and which cigars are exempt as "premium cigars." Manufacturers control the process of manufacturing the cigar and the different types of tobacco leaf used in the production of these products. Thus, manufacturers have the greatest ability to determine whether a product meets the proposed exclusionary criteria when it leaves the factory. Retailers are largely dependent on the representations made by manufacturers, but are ultimately responsible for how the product is sold, including the retail price. However, both retailers and manufacturers (as well as distributors and importers) bear potential legal liability if a "covered cigar" is improperly sold as a "premium cigar."

Each element of FDA's proposed definition of a "covered cigar" is presented below in bold font. IPCPR provides comments for each element of the definition.

Covered cigar means any cigar, as defined in this part, except a cigar that:

(1) Is wrapped in whole tobacco leaf;

IPCPR supports this element. This concept was proposed as part of IPCPR's definition of a premium cigar in the IPCPR 2011 Citizen Petition (although the exact wording used in the aforementioned document was "wrapped in leaf tobacco"). IPCPR's phrase was taken verbatim from the definition of a "cigar" at 26 U.S.C. § 5702(a) (Internal Revenue Code) and the definition of "little cigar" at 15 U.S.C. § 1332(7) (Federal Cigarette Labeling and Advertising Act). Like FDA's proposed definition, it specifically excludes products with a homogenized tobacco wrapper. A leaf tobacco wrapper is easily visualized, and does not require sophisticated analysis. Thus, FDA and other government inspectors, retailers, importers, distributors, and consumers can identify the type of product at issue.

(2) Contains a 100 percent leaf tobacco binder;

IPCPR supports this element. Like the proposed whole leaf wrapper, a requirement for a leaf tobacco binder would exclude products with a homogenized tobacco binder. Although a binder is not as easily visualized as a wrapper, it could potentially help FDA and other government inspectors, retailers, importers, distributors, and consumers to identify the type of product at issue.

(3) Contains primarily long filler tobacco;

IPCPR supports this element. However, FDA should be aware of several issues that may affect the regulatory utility of this element. "Long filler" is a term used in the industry to describe a cigar filled with predominately whole tobacco leaves that run the length of a cigar. Most premium cigars use only long filler tobacco. However, several factors make it difficult to regulate cigars on the basis of filler type. First, when a torcedore makes a cigar, sometimes he or she will break a piece of the long filler to make an adjustment. The breaking process means that some portion of the cigar filler will not be composed of

whole tobacco leaves. Second, as noted in the proposed regulation, it is difficult to quantify "primarily," and the proposed deeming regulation does not provide such a definition.

Long filler tobacco is not easily visualized. To determine filler content the cigar must be disassembled, which will likely break some of the filler tobacco leaves. Ultimately, there is no simple, reliable test to determine whether a cigar is "primarily long filler," which could be problematic for FDA inspectors, retailers, and consumers.

Unreliable testing combined with a vague requirement that the product must be "primarily" long filler allows IPCPR to conclude that both compliance and enforcement of this element will be difficult. If this becomes an element of the definition of a "premium cigar," a retailer must be able to rely on a manufacturer's representation (e.g., through appropriate labeling, as discussed in section III.B. below) that the product "contains primarily long filler."

(4) Is made by combining manually the wrapper, filler, and binder;

IPCPR supports this element. Most of IPCPR's retail members are experienced tobacconists who can readily determine whether a product is "hand rolled" (or, "combined manually"). Less experienced retailers, however, may not be able to determine whether a cigar is "made by combining manually the wrapper, filler, and binder," particularly if a manufacturer represents that it is. Because manufacturers have control over the manufacturing process, a retailer must be able to rely on a manufacturer's representation (e.g., through appropriate labeling, as discussed in section III.B. below) that the components of the cigar were manually combined.

(5) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;

IPCPR supports this element. The presence of a filter, tip, or non-tobacco mouthpiece is easily visualized, and does not require sophisticated analysis. Thus, FDA and other government inspectors, retailers, importers, distributors, and consumers can more readily determine the type of product at issue. However, although premium cigars are currently "capped by hand," that feature may not be immediately obvious to an untrained eye. This could lead to both enforcement and compliance issues, and FDA should consider that issue moving forward. A retailer must be able to rely on a manufacturer's representation (e.g., through appropriate labeling, as discussed in section III.B. below) that the cigar was "capped by hand."

(6) Has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment);

IPCPR opposes this element. There are several problems with including an explicit cost in the definition of a "covered cigar." The chief difficulty is that retail cost is controlled primarily by retailers. For example, if a retailer sells a cigar for less than $10 that the manufacturer intended to be "premium," would the manufacturer have then made a "covered cigar?" This could expose the manufacturer to legal liability. A second difficulty is that sales tax rates and "other tobacco product" ("OTP") or excise tax rates vary greatly between states. Those excise taxes range from three to 40.5 cents per ten cigars (Alabama) to nothing (Florida) to ten percent of the manufacturer's price (Missouri) to 75 percent of the wholesale price (New York) to 95 percent of the wholesale price with a $3.50 tax cap (Minnesota). These variances, both in amount and in the timing of the assessment, affect the retail price of a cigar, resulting in a great variance in retail price between states for the same cigar. In addition, retail price of all goods is affected by geography, since retail prices tend to be higher in large cities than in rural areas. Thus, some cigars will be designated based solely on where they are sold. IPCPR is not aware of a specific retail

price being an element of regulation by FDA of any other product, even cigarettes, and FDA has not explained why it is appropriate to target premium cigars.

Finally, the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)("Tobacco Control Act"), includes this restriction on retailer records: "The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption." 21 U.S.C. § 387t(b)(5). It is not clear how FDA would enforce a retail price element given this apparently general prohibition.

(7) Does not have a characterizing flavor other than tobacco;

IPCPR accepts this element in principal, but notes that "characterizing flavor" has not been defined in the context of tobacco products, and is not defined in the proposed deeming regulation. To the extent that FDA wants to propose a definition of "characterizing flavor" through future notice and comment rulemaking, which is the appropriate venue for such a discussion, IPCPR looks forward to providing comments through that process. For example, using the precedent set by FDA's food regulations (*see* 21 C.F.R. § 101.22(i)), unless a tobacco product claims to have a characterizing flavor in labeling or advertising, the mere presence of flavoring ingredients should not affect the regulation of the product.

(8) Weighs more than 6 pounds per 1000 units.

IPCPR believes that it is appropriate to use "weight" as a definitional component of cigars, as this has already been established for purposes of taxation.[1] Furthermore, it should be noted that the proposed definition is double the weight necessary to qualify as a "large cigar" for purposes of taxation, further limiting the class. The weight of a cigar is readily determined, which will help FDA and other government inspectors, retailers, importers, distributors, and consumers to more easily determine the type of product at issue.

III. Additional Comments Regarding FDA's Proposed Definition of "Covered Cigar"

A. FDA Should Consider Simplifying and Reducing the Number of Elements That Would Qualify a Cigar as an Exempt "Premium" Cigar

IPCPR shares FDA's concerns that "any attempts to create a subset of premium cigars that are excluded from regulatory authority might sweep other cigar products under its umbrella." 79 Fed. Reg. at 23,150. However, FDA should share IPCPR's concerns that unnecessary overregulation of premium cigars will also have a devastating effect on manufacturers and retailers, particularly small businesses. Given that FDA has no experience enforcing and industry has no experience complying with such regulations, IPCPR believes that it is most appropriate to begin with simple, easy to understand regulations, including the elements of the "covered cigar" definition. This approach will allow FDA and industry to gain both experience and additional information on the effects of regulation. If the initial "umbrella" is later deemed to be too large, FDA can always amend the regulations to capture the products for which additional regulation is appropriate. However, if the "umbrella" is too small from the beginning, many retail tobacconists will be forced out of business.

---

[1] For purposes of taxation, "cigars" are already classified as "small" or "large." Small cigars weigh "not more than 3 pounds per thousand," whereas large cigars weigh "more than 3 pounds per thousand." 26 U.S.C. § 5701.

Accordingly, IPCPR believes that FDA should begin with a subset of the elements proposed, and not include elements that would complicate both enforcement and compliance. In particular, both retail price and "characterizing flavor" seem particularly vague and arbitrary, presenting both enforcement and compliance difficulties.

B. FDA Should Establish by Regulation a "Safe Harbor" Whereby a Retailer Can Rely on a Manufacturer's Representations Regarding the Regulatory Elements of the Cigar

Under either Option 1 or Option 2, FDA would make manufacturers, distributors, importers, and retailers all liable for the actions of one another. Proposed 21 C.F.R. § 1140.10 reads:

> **General responsibilities of manufacturers, distributors, and retailers.**
>
> Each manufacturer, distributor, importer, and retailer is responsible for ensuring that the cigarettes, smokeless tobacco, or covered tobacco products it manufactures, labels, advertises, packages, distributes, imports, sells, or otherwise holds for sale comply with all applicable requirements under this part.

79 Fed. Reg. at 23,204.

This is fundamentally unfair, particularly considering the definition of a "covered cigar" posed by FDA in Option 2. Manufacturers control the different types of tobacco leaf used in the manufacture of the product, and the process of manufacturing the individual cigar, and thus have the greatest ability to determine whether a product meets the proposed exclusionary criteria when it leaves the factory. Retailers are ultimately responsible for how the product is sold, including the retail price.

IPCPR notes that retailers, particularly small or less experienced retailers, may not be able to determine whether a premium cigar meets all of the elements of the definition in the proposed deeming regulations. Because the cigar manufacturer has the greatest ability to determine the materials and means of manufacture, IPCPR believes that FDA should consider limiting the manufacturers' use of the word "premium" or phrase "premium cigar" only to describe cigars that meet all elements of the final definition. For example, a manufacturer could label a cigar or box of cigars as "premium" only if the product complies with all elements of the regulatory exemption, and any other use of the word should be considered misbranding. A retailer must be able to rely on the manufacturer's representation of the product, and not be subject to liability if it is later determined that the manufacturer improperly labeled a "covered cigar" product as "premium." FDA established a retailer "safe harbor" for required warning labels and advertising in the proposed deeming regulations, and FDA should apply the same logic to the retailer's responsibilities for determining whether a product meets the regulatory requirements for an exemption (i.e., whether a cigar is a "premium cigar").

IV. Additional Comments Regarding FDA's Proposed Deeming Regulation

A. Public Health Effects of Premium Cigars are Different than Mass-Market Products Because of Different Usage Patterns, and Thus FDA Should Regulate the Two Categories of Products Differently

Premium cigars should be exempted from regulation given that they have different usage patterns than mass-market tobacco products. Usage data show that premium cigars products are consumed infrequently, often in a celebratory nature, by adults. Premium cigars are also used at a much lower rate than cigarettes, smokeless tobacco, or non-premium cigars. According to a survey conducted by Cigar

Aficionado magazine in May 2009, 43% of respondents smoke two cigars or less per week and 36% reported smoking 3-6 cigars per week (survey data on file). In contrast, most cigarette smokers, for example, smoke daily.

Accordingly, IPCPR believes that FDA's final regulations should not take a one-size-fits-all approach to the regulation of a diverse suite of tobacco products, and should instead impose regulatory requirements for premium cigars consistent with recognized public health differences. IPCPR agrees with FDA's recognition of the risk continuum and believes that FDA should establish a regulatory structure that distinguishes between products on different points of the continuum, as recognized by Option 2. Premium cigars should be exempted from regulation within the scope of the final rule under Option 2, taking into account the revised definition identified above. Should FDA choose to establish some form of regulation, we strongly believe that any rules covering premium cigars should be tailored to match the unique characteristics and public health profile of these unique, artisan products.

B. Studies Indicate That Underage Youths Do Not Smoke Cigars to an Appreciable Extent, and This Should Inform FDA's Decision About Whether to Regulate Premium Cigars

The most current research demonstrates that underage adolescents do not smoke premium cigars to an appreciable degree, and therefore inappropriate "youth access" should not be a consideration when it comes to premium cigars.

The Tobacco Control Act provides that, among its purposes, is to grant FDA "the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco," while at the same time "to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure they are not sold or accessible to underage purchasers." Tobacco Control Act §§ 3(2), 3(7) (emphasis added). The Tobacco Control Act also expressly deprives FDA of authority to issue any regulation "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco or all roll-your-own tobacco products." 21 U.S.C. § 387g(d)(3)(A). Thus, the statute seeks to balance the public interest in limiting underage exposure to tobacco products, while preserving access to legal tobacco products of choice by adults. FDA may not neglect the latter purpose to fulfill the former, as both are congressionally mandated objectives.

It should be recognized that the purchase or attempted purchase of tobacco products by minors is not a significant issue for premium cigar shops. Firstly, the premium products sold at IPCPR shops are generally not affordable to youth. Secondly, sales in our members' stores are a face-to-face transaction, and in the rare event that an adolescent might try to purchase a tobacco product from a cigar store, the salesperson (frequently the owner of the store) is required to verify the age of the customer. In addition, each new member of IPCPR receives a "We ID" package of signage to use at the point of sale. Thirdly, our members' shops are subject to state and local regulation of tobacco sales, which have proven more than adequate to control underage access to tobacco products from our members' establishments. IPCPR is proud of the compliance record of its members. As FDA noted in the proposed deeming regulations, the Office of the Inspector General for the Department of Health and Human Services ("OIG") has concluded that minors are not attracted to premium cigars, but prefer lower cost and more readily accessible tobacco products. 79 Fed. Reg. at 23,151 (quoting OIG, *Youth Use of Cigars: Patterns of Use and Perceptions of Risk*, OEI-06-98-00030 (Feb. 1999).

FDA should explain more thoroughly why data regarding "young adult males and teenagers" is relevant to underage "youth access" to tobacco products. Notably, FDA cited "a recent analysis of cigar use by young adults (aged 18 to 29) . . . providing preliminary confirmation that young adults do use

premium cigars." 79 Fed. Reg. at 23,151. Fundamentally, tobacco products, including premium cigars, are legal in adults over the age of 18. Elsewhere, the proposed deeming regulation states: "The 2010 National Survey on Drug Use and Health found that over 1 in 10 young adults (ages 18–25 years old) smokes cigars (Ref. 54 at 146, Table 3.5b)." *Id.* at 23,158. As noted above, cigars are legal in that age group.

However, there is data, not discussed in the proposed deeming regulation, regarding actual underage use. Nowhere is this omission more evident than in the proposed deeming regulation's lack of discussion regarding the most recent government data available regarding tobacco product use, released by another agency within the Department of Health and Human Services: The Substance Abuse and Mental Health Services Administration ("SAMHSA"). SAMSHA, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795 (2013) (the "SAMHSA Report"). Figure 4.2 from the SAMHSA Report shows past month tobacco use in youth, ages 12-17 from 2002-2012, which is the underage group that FDA states that it is most concerned about. Figure 4.2 reveals several important facts. Firstly, use of all tobacco products has fallen consistently in this age group from 2002-2012. Secondly, it should be noted that this substantial decrease in tobacco use occurred in the period before FDA obtained jurisdiction over cigarettes and smokeless tobacco. Whether FDA's subsequent activities regarding the regulation of cigarettes and smokeless tobacco will affect this consistent decline in underage use remains to be seen, but FDA should wait to see the results of its efforts before proposing to regulate additional tobacco products. Finally, Figure 4.2 shows that "cigar" use (type of cigar not defined) has never exceeded 5% in any year, and in the last year measured had fallen to 2.6%. A minimal degree of underage use of an otherwise legal product is unavoidable, perhaps for reasons discussed in the proposed deeming regulation (i.e., underage users may obtain tobacco products from social sources such as friends or parents, or from stealing tobacco from parents or others). 79 Fed. Reg. at 23,161. Given the minimal use that actually occurs, a more measured degree of regulation, particularly for premium cigars, would be more appropriate than Option 1 in the proposed deeming regulation.

C. Age Restrictions and Verification Requirements are Appropriate for All Tobacco Products Including Premium Cigars, but a Prohibition on Free Samples is Not Appropriate or Necessary to Prevent Youth Access to Premium Cigars

IPCPR believes that age restriction and verification requirements are reasonable regulatory steps for all tobacco products, including premium cigars sold face-to-face in our members' stores. IPCPR is proud of our organization's and our individual member's constant efforts to help prevent underage access to tobacco products. Each new member of IPCPR receives a "We ID" package of signage to use at the point of sale. Every member of IPCPR is offered free courses through Tobacconist University, IPCPR's Official Education Provider, to become a Certified Retail Tobacconist. The very first obligation under The Code of Ethics & Standards for a Certified Retail Tobacconist is to: "Obey and enforce all local, state and federal laws regarding tobacco age/use restrictions."

The reason given by FDA for imposing a prohibition on free samples is simply not relevant to premium cigars. FDA states that such a prohibition:

> [W]ould eliminate a pathway for youth to access tobacco products, reducing youth initiation and therefore short-term and long-term morbidity and mortality resulting from these products. The Institute of Medicine (IOM) has stated that free samples of cigarettes 'encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity' (Ref. 26). While the IOM was speaking in the context of

> cigarettes, the same rationale would apply to the proposed deemed products.

Id. at 23,149.

As IPCPR has explained to FDA on several occasions, the same rationale does not apply to premium cigars. In contrast to the historical distribution of free cigarettes, sampling of premium cigars most frequently occurs in a controlled environment, namely, the tobacconist's shop. The professional tobacconist controls who is provided the sample, and requires proof of age. Unlike cigarette smokers, premium cigar smokers exhibit little brand loyalty and "sampling events" are frequently held in premium cigar shops as social occasions to introduce adult premium cigar smokers to limited edition products, seasonal offerings, new brands and varieties, and promote the shop. Often, these sampling events are tied to local community charities. A ban on such practices would have an immediate and significant adverse effect on many small businesses. Sampling is also critically important for premium cigar manufacturers, which frequently introduce new products at much higher price points than other types of cigars. Adult consumers should be permitted to try an expensive new product before they buy it. In addition, IPCPR organizes a trade show for its members where sampling takes place so that retailers can test new products from the manufacturers of premium cigars. We estimate that this annual event creates an economic impact in excess of $15 million to the host city and generates over $750,000 in tax revenues. The show is IPCPR's largest source or revenue. If sampling were banned, IPCPR would likely cease to exist in its present form, leaving a small business industry fragmented without a centralized source of education as to compliance and best practices.

Moreover, a ban would have no effect on the public health since there is no evidence that underage children are obtaining premium cigars from any source to an appreciable extent, much less that sampling is an avenue to such access as demonstrated in the SAMHSA Report.

D. The Proposed Warning Statements Should Not Be Required for Individual Cigars

IPCPR agrees that because premium cigars are frequently sold to adult consumers individually, it would not be practical to require a health warning for such cigars. *Id.* at 23,181. We also note that Option 2 would exempt premium cigars from certain labeling requirements, particularly the requirement that would require warnings on 30% of the principal display panels. Premium cigars are usually packed in decorative boxes, which our customers have come to appreciate as part of the buying experience. As retailers, our humidors are filled with those ornate boxes. Covering 30% of each box with a required warning is more than excessive, particularly when combined with the requirement for a warning sign at the point of sale. In addition, FDA has offered no evidence that requiring a warning covering 30% of a cigar box or 20% of advertising will lead to any appreciable public health benefit. Accordingly, we support the comments of others who have opposed the required warnings.

E. FDA's Economic Impact Analysis Demonstrates That the Financial Burdens Under Option 1 Will be Devastating

FDA estimates that as a result of the costs imposed on manufacturers of premium cigars under Option 1, up to 50% of handmade cigar products will cease to be marketed in the United States. Economic Impact Analysis at p. 26. FDA also notes that small businesses will be most affected by Option 1 and that "some firms may exit the market." *Id.* at 67. Only Option 2 protects the small premium cigar manufacturers and by extension, the IPCPR retailers who sell their products. IPCPR is concerned about the protecting the range of products its members will be able to offer to their adult customers. Being small businesses, our members must have a variety of premium cigar products to offer adult

customers at various price points if they are to survive. Accordingly, IPCPR agrees with the economic impact analyses provided in the comments submitted by others.

F. IPCPR Supports An Exemption For Cigars Rolled Using Hand-Operated, Vintage Cigar Machines

IPCPR includes as an attachment our comments in support of an exemption for cigars rolled using hand-operated, vintage cigar machines. There are three small factories left in the United States producing a very small number of cigars in this manner and an exemption would protect US jobs. IPCPR agrees with the comments submitted by the JC Newman Company, and others regarding extending the exemption to these cigars. IPCPR also wishes to take this opportunity to express its appreciation for the many members of Congress who have supported an exemption for premium cigars including cigars rolled using hand-operated, vintage cigar machines as expressed in H.R. 792 and S. 772.

* * * *

IPCPR appreciates having this opportunity to comment on the proposed deeming regulation.

Sincerely,

Finnie Helmuth
President
International Premium Cigar & Pipe Retailers Association

Craig Cass
First Vice President
International Premium Cigar & Pipe Retailers Association

Mark Pursell
CEO
International Premium Cigar & Pipe Retailers Association

Phone: 706-494-1143
Fax: 706-494-1893
website: www.ipcpr.org
email: info@ipcpr.org

#4 Bradley Park Court Suite 2H
Columbus, Georgia 31904-3637

August 7, 2014

VIA ELECTRONIC FILING

Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2014-N-0189

Dear Sir or Madam:

The International Premium Cigar & Pipe Retailers Association ("IPCPR") understands there are three historic factories in America that still roll cigars using hand-operated, vintage cigar machines:

- Avanti Cigar Co. in Dunmore, Pennsylvania
- J.C. Newman Cigar Co. in Tampa, Florida
- National Cigar Co. in Frankfort, Indiana

These factories make a fraction of the cigars sold annually in the United States, but are historic and family owned. IPCPR believes that hand-operated, vintage machine-made cigars should be treated the same as premium cigars because they have the same look, feel, smell, and taste as value-priced handmade cigars. They have the same style of packaging, and have similar retail prices. They are often sold by IPCPR members, on the same shelves as other value-priced premium cigars. Like premium cigars, they present minimal public health and youth access issues, and consumers perceive these cigars to be just like value-priced premium cigars.

As vintage machine-made cigars are wrapped in 100% natural leaf tobacco, they look very different from modern mass-market machine-made cigars, which have a homogenized tobacco wrapper. Vintage machine-made cigars are also sold in different retail outlets at different price points, and have a different type of consumer than modern mass-market cigars. Moreover, hand-operated, vintage cigar machines roll approximately 840 cigars per hour, a small fraction of the 225,000 cigars per hour made by modern mass-market cigar machines. It would be cost-prohibitive or technically impossible (and defy logic) for mass-market cigar companies to slow their machines from 225,000 cigars per hour to less than 1,500 cigars per hour or to than 1% of their current rate in an attempt to evade regulation.

As FDA knows, IPCPR has long supported a statutory exemption for premium cigars. The current form of the proposed legislation is the Traditional Cigar Manufacturing and Small Business Jobs Preservation Act (H.R. 792 and S. 772, which are identical bills). This proposed legislation would exempt both handmade premium cigars, and hand-operated, vintage machine-made cigars made in the United States from FDA regulation. The bill defines the "hand-operated machine made" cigar as:

> A]ny roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and . . . has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar; and does not include a cigarette (as such term is defined by section 900(3)) or a little cigar (as such term is defined by section 900(11)).

H.R. 792, 113th Cong. § 2(a) (2013).

This definition is narrowly tailored to include only the hand-operated, vintage machine-made cigars from these American factories. Due to the high costs and limited supply of 100% natural leaf tobacco wrappers, it would, without a doubt, be cost prohibitive for mass-market cigar makers to change their production processes to meet this definition. More importantly, the process cannot be used by other companies. These cigars should be treated as FDA determines to treat cigars that meet the "premium" definition.

* * * *

IPCPR appreciates having this opportunity to comment on the proposed deeming regulation.

Sincerely,

Finnie Helmuth
President
International Premium Cigar & Pipe Retailers Association

Craig Cass
First Vice President
International Premium Cigar & Pipe Retailers Association

Mark Pursell
CEO
International Premium Cigar & Pipe Retailers Association

Exhibit 19

CRA

CIGAR RIGHTS OF AMERICA

FIGHTING FOR THE FREEDOM TO ENJOY PREMIUM CIGARS

August 8, 2014

Submitted via www.regulations.gov
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Food and Drug Administration Docket No. FDA-2014-N-0189, RIN 0910-AG38, Deeming Tobacco Products to Be Subject to the Federal Food Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act

To Whom It May Concern:

Cigar Rights of America ("CRA") submits its comments on the Food and Drug Administration's ("FDA") proposed regulations that would deem additional tobacco products subject to the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), as amended by the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"). CRA serves as the sole voice of premium cigar consumers in the United States of America on matters of legislative and regulatory concern, with a membership that spans all 50 states. In addition, CRA members also include professional retail tobacconists that dot "Main Street America," and serve as an historic and social component of the community fabric for those who enjoy premium cigars. However, the cornerstone of CRA is that it is the largest preeminent coalition of premium cigar manufacturers in the world, with representation of over 60 diverse artisan producers of hand-made premium cigars. This coalition ranges from those that conduct business on an international scale, to the single proprietorship craftsman, who simply wants to produce great hand-made premium cigars. The coalition also includes the entire spectrum of the supply chain, including distributors, growers, mail-order houses, logistics, and associated supporting enterprises. The manufacturer members of CRA are predominantly family owned and entrepreneurial small businesses, built upon the skills that have often been passed down from generation to generation.

CRA concurs with the FDA's proposed "Option 2" that would exempt a defined category of premium cigars from regulation under the Tobacco Control Act. CRA also concurs with the

"Option 2" definition of an exempted cigar, with the narrow exception of the $10 per cigar retail price qualifier.

Introduction

Premium cigars are readily differentiated from cigarettes and other tobacco products based on their demonstrable lack of public health and youth access issues. We applaud the FDA's recognition of these differences in the so-called "Option 2." Premium cigars should not be subject to regulations akin to those applicable to cigarettes and other tobacco products, where the disease risk is well known and the history of youth access is well documented.

Our comments first discuss the premium cigar industry. We highlight the differences between premium cigars and other tobacco products. Those differences compel exempting premium cigars from FDA regulation. The typical premium cigar smoker has negligible health risks, even compared to non-smokers. In addition, there is no strong evidence of youth access, which makes sense in light of premium cigars' special characteristics that are not attractive to minors and overall lack of youth appeal and existing laws nationwide, which make sales to minors illegal. Premium cigar manufacturers and retailers are dedicated to enforcing these important laws.

In the next section, we discuss the appropriate definition of a premium cigar for purposes of an exemption from the FDA's jurisdiction. CRA strongly opposes Option 1, but supports the Option 2 definition for exemption. However, we have significant issues with the proposed $10 per cigar retail price qualifier, as it would subject the vast majority of premium cigars to regulation and would submit premium cigar manufacturers and importers to third-party retailers' pricing decisions and create a complicated enforcement landscape.

We next comment on particular aspects of the FDA's proposal. Although we do not believe that any form of FDA regulation would be appropriate, we have particular concern with the proposed premarket approval requirement for cigars introduced, or changed in any way, since 2007. This covers virtually all premium cigars, which are artisanal products that are constantly changing. The premium cigar industry finds that it would be prohibitory due to cost restrictions, production standards and practices, market demands and nuances such as the naturally evolving characteristics of natural tobacco, for the FDA to enforce the proposed premarket approval procedures. It is difficult to imagine that the framers of the Tobacco Control Act contemplated premium cigars in formulating these requirements, which are geared toward mass-produced, entirely homogenous products. In fact, many members of Congress who voted in favor of the Tobacco Control Act have expressed agreement with this viewpoint to FDA and OMB, and by supporting clarifying legislation.

Finally, we discuss the economic impact of the proposed regulations on the premium cigar industry and related entities. In drafting the proposed regulations, the FDA evidently neglected to thoroughly consider this issue, notwithstanding the FDA's obligations under the Regulatory Flexibility Act and Executive Order 12866. It is clear that the congressional intent of the Tobacco Control Act was designed to address two primary issues of public health concern – youth access and the disease risk associated with certain tobacco products. The premium hand-

made cigar sector does not meet this test of legislative or regulatory concern, and hence should be afforded the exemption outlined through Option 2.

FDA regulation would devastate the industry, at a minimum forcing manufacturers to cease popular "special releases," curtailing their product offerings, and forcing adult consumers to pay dramatically higher prices for the products they choose to enjoy. The premarket approval standards set forth in the proposed regulations would shutter the limited release, special edition and collector segment of the premium cigar market, given that such product releases occur on an annualized basis and represent a significant portion of the annual economic benefit and consumer enjoyment for retailers and manufacturers alike. Given the time frame for projected approval processes for this segment of the market, such FDA mandates would eliminate and act as a *de facto* ban. The FDA also has obviously failed to consider the downstream impacts of the proposed regulations, not just on tobacco product manufacturers and importers, but also distributors, retailers, suppliers, trade show proprietors, and workers everywhere that depend on this industry as a way of life.

Premium Cigars and the Premium Cigar Industry

Premium cigars comprise a very small fraction of the United States tobacco market. Accordingly to publicly available data from the Alcohol and Tobacco Tax and Trade Bureau of the U.S. Treasury Department ("TTB"), the cigarette industry produced about 300 billion cigarettes in 2013. See Alcohol and Tobacco Tax and Trade Bureau, 2013 – Tobacco Products Monthly Statistical Releases, http://www.ttb.gov/statistics/13tobstats.shtml. The cigar market (large and small cigars) was about 4.4 percent of the cigarette market, with about 13.1 billion cigars produced in 2013 according to TTB data and survey data from the Cigar Association of America.[1] Of these 13.1 billion cigars, premium cigars accounted for only about 300 million. Thus, premium cigars account for less than three percent of the U.S. cigar market, and less than a tenth of a percent of the U.S. tobacco market.

Unlike the rest of the tobacco industry, with a few major manufacturers and relatively few brand offerings, the premium cigar industry is much less consolidated with many brand offerings. Four major manufacturers control more than 90 percent of the cigarette market. Those manufacturers offer roughly ten to twenty brands each. By contrast, there are hundreds of premium cigar manufacturers and importers, particularly when one considers the many individuals who hand-roll cigars and who would be considered "tobacco product manufacturers" potentially subject to the FDA's requirements. A typical premium cigar manufacturer may have

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[1] The Tobacco Control Act does not define the term "cigar," although it does define a "little cigar." See 21 U.S.C. § 387(11). The Internal Revenue Code generally defines a "cigar" as a roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco, which would include homogenized tobacco paper. See 26 U.S.C. § 5702(a). "Large cigars" and "small cigars" are differentiated based on their weight for federal tax purposes, with large cigars weighing more than three pounds per thousand, and small cigars weighing three pounds per thousand or less. See 26 U.S.C. § 5701(a). Premium cigars account for a very small fraction of all "large cigars" sold in the United States, with the remainder primarily being machine-made, filtered cigars wrapped in homogenized tobacco paper.

more than fifty to almost one hundred SKUs / brand offerings based on the products' various shapes and sizes. Premium cigar manufacturers also commonly offer "limited editions" and "special releases" that may consist of a one-time distribution of only a few hundred boxes.

Cigarettes are homogenous products; they are uniformly manufactured and packaged. By contrast, due to the manual nature of the manufacturing process, premium cigars are not uniformly manufactured or packaged. Cigarettes are machine-made with a standardized process. Premium cigars are manufactured by hand. The process is not standardized or uniform, with many different cigar shapes and lengths.

The manufacture of a single premium cigar is a complicated, time-consuming process. This artisanal process typically takes at least three to five years from the time the tobacco seed is planted until the cigars are boxed for delivery. In the course of producing premium cigars, human hands may touch the tobacco leaf hundreds of times during the manufacturing process. Due to crop and product changes, manufacturers frequently alter a product's composition to maintain product quality and consistency.

The premium cigar consumer is also different from the typical tobacco consumer. Unlike cigarette consumers, who are intensely brand-loyal, the typical premium cigar consumer often buys a variety of brands in one visit. Because of this, it is important for premium cigar manufacturers to offer many varieties, and it is common for premium cigar manufacturers to change their product offerings. New products are integral to this industry.

The typical premium cigar smoker is also much older than typical consumers of cigarettes and other tobacco products. Although studies of tobacco consumer age demographics generally have not focused on premium cigars, at least one survey has. In 2007, *Cigar Aficionado*, the leading magazine for the premium cigar consumer, conducted a survey of its readership. That survey shows that the typical premium cigar smoker is over 40. More than 70 percent of the magazine's readership is age 40 and older. A well-known retailer, Holt's Cigar Company, conducted its own survey, which indicated an even older typical consumer. That survey of 10,000 of Holt's Cigar Company's customers reflected an average age of 54.7.

Premium Cigars Should Not Be Regulated Under the Tobacco Control Act

Premium cigars should not be subject to FDA regulation because they do not share the youth access and public health issues posed by other tobacco products.

By its very terms, the Tobacco Control Act applies only to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." Section 901(b). Any other "tobacco product" that FDA may wish to regulate must be brought into the Tobacco Control Act by regulation. Id. Although "cigarette" and "little cigar" are defined in the Tobacco Control Act (section 900(3) and 900(11), respectively), the term "cigar" is not. Thus, Congress recognized that cigars do not pose the same public health concerns requiring immediate attention by the FDA.

The purposes of the Tobacco Control Act include ensuring that the FDA "has the authority to address issues of particular concern to public health officials, especially the use of

tobacco by young people and dependence on tobacco" while at the same time "to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure they are not sold or accessible to underage purchasers." Tobacco Control Act, Section 3 (emphasis added). A premium, hand-rolled cigar may be a tobacco product under the Tobacco Control Act, but there is no evidence that suggests premium hand-made cigars carry the level of risk associated with cigarettes and other regulated tobacco products. And although the FDA may have the authority to regulate all "tobacco products," nothing in the Tobacco Control Act obligates it do to so.

Premium cigars are different from other tobacco products currently subject to FDA regulation, a distinction that the FDA has previously recognized. In 1995, when the FDA first issued a rule asserting regulatory authority over cigarettes and smokeless tobacco, cigars were expressly exempted. The FDA stated:

> FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominately use cigarettes and smokeless tobacco products.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 60 Fed. Reg. 41314, 41322 (Aug. 11, 1995).

In rejecting comments that urged the FDA to regulate cigars, the FDA stated that "there is insufficient evidence of cigar or pipe tobacco use by children and adolescents to support the inclusion of cigar[s] . . . within the scope of the final rule." Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44369, 44421-22 (Aug. 28, 1996).

Nothing has changed since then. There is still no evidence that minors use premium cigars in significant quantities. In fact, as recently as July 2012, the House Appropriations Committee reminded the FDA that "premium cigars have unique characteristics and cost-prohibitive price points and are not marketed to kids" and that "[a]ny effort to regulate cigars should take these items into consideration." H.R. Rep. No. 112-542, at 46 (2012).

More recently, Congress has signaled its intent that FDA should not regulate premium cigars. On February 15, 2013, the U.S. House of Representatives introduced the Traditional Cigar Manufacturing and Small Business Jobs Preservation Act, which proposes to amend the FD&C Act to remove premium cigars from the FDA's jurisdiction. H.R. 792 (2013). The bill has 162 cosponsors. On April 18, 2013, the U.S. Senate introduced Senate Bill 772 as a companion bill to House Bill 792. S. 772 (2013). The Senate bill has 16 cosponsors. The 2012 versions of these bills respectively had 221 (a majority of the House) and 14 cosponsors. We have attached as Exhibit A various letters from our supporters in Congress.

Exempting premium cigars from FDA regulation is consistent with premium cigar consumer age demographics, premium cigar consumption patterns and the relative lack of

disease risk. Each of these issues is discussed in turn below, as well as the obligation of the FDA to direct its limited resources for maximum effectiveness.

Premium Cigar Age Demographics

As noted above, there is no statistically significant evidence that minors use premium cigars in any significant quantities. The FDA's proposal certainly does not cite any such evidence. In fact, youth consumption of cigars has declined significantly over the last ten years. Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings (2012) (showing that cigar youth declined from 4.8 percent in 2004 to 2.6 percent in 2012).

The proposed regulations' only cited authority addressing premium cigar consumer age demographics does not address underage consumption at all. That non-peer-reviewed study, "Use of Flavored Cigars, Cigarillos, and Little Filtered Cigars," addresses consumption patterns of several cigar types across several age groups, and is cited for the proposition that "premium cigar use is being reported by young adults and that such use is not restricted to older adults."

However, of the "young adults" (individuals aged 18 to 29 which are of legal age in the overwhelming majority of jurisdictions in the United States) referenced in the survey, only a very small percentage smoke premium cigars. The study reports that 16.3 percent of young adults smoke cigars, defined to include little filtered cigars, cigarillos, large cigars and premium cigars. Of that group, about 15 percent were identified as premium cigar smokers. Thus, only about two percent of the "young adults" were identified as premium cigar smokers.

Although proponents of regulation may cite studies alleging cigar youth consumption rates in general, those studies suffer the critical defect of failing to distinguish among cigar types. The National Cancer Institute (NCI) has recognized that distinctions between premium cigars and other types of cigars have historically been ignored in scientific research about cigar smokers: "Few surveys have questioned cigar smokers about the quantity and type of cigars typically consumed." National Cancer Institute, Smoking and Tobacco Control Monograph 9: Cigars: Health Effects and Trends, at 27 (1988) ("Monograph 9"). Thus, it is misleading to speak of prevalence and rate changes in "cigar consumption" in any age group, particularly adolescents, without making appropriate distinctions between cigar types. CRA has suggested to the Centers for Disease Control and Prevention that it include more specific questions pertaining to cigar consumption in future surveys.

References addressing youth consumption rates for "cigars" are likely misleading due to apparent youth preferences for machine-made and/or filtered cigars. "Manufactured cigars, rather than premium cigars, are most commonly used by teens." Department of Health and Human Services, Youth Use of Cigars: Patterns of Use and Perceptions of Risk (1999). This survey showed that the most popular brands among youth were all machine-made, non-premium cigars. This makes sense, because premium cigars are more expensive than other cigars, and price plays a significant role in youth product preferences. Delnevo, C.D., J. Foulds, M. Hrywna, "Trading Tobacco: Are Youths Choosing Cigars Over Cigarettes?," American Journal of Public Health, 95: 2123, 2005.

Similarly, when studies speak of consumption increases in "large cigars," this is a function of a recent federal excise tax changes, and not due to any increased popularity of premium cigars. In 2009, Congress passed the Children's Health Insurance Program Reauthorization Act ("CHIPRA"), CHIPRA increased federal excise taxes on small cigars from $1.83 per thousand to $50.33 per thousand, a 2,700 percent increase. This caused many manufacturers to slightly increase the weight of their products to qualify for the lower taxes levied on large cigars. See United States General Accounting Office, Tobacco Taxes: Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes, at 20 (2012). Thus, any increases in large cigar sales are not attributable to increased popularity of premium cigars, but rather a tax disparity created by CHIPRA. See Campaign for Tobacco-Free Kids, Not Your Grandfather's Cigar, at 4 (2013). In fact, premium cigar sales actually decreased in the years after CHIPRA. Id.

When studies do address premium cigars, they show that youth do not consume premium cigars in significant quantities. A recent study addressed cigar brand preferences among minors. See Delnevo C.D., D.P. Giovenco, B. K. Ambrose, et al., "Preference for Flavoured Cigar Brands Among Youth, Youth Adults and Adults in the USA," Tobacco Control , doi:10.1136/tobaccocontrol-2013-051408; 1-6, 2014. The study shows that minors overwhelmingly prefer machine-made and/or filtered cigars, and not premium cigars. Id. at 4. They do not prefer premium cigars. Id. In fact, six machine-made brands accounted for more than 85 percent of the brands preferred by youth. Id. Premium cigar brands accounted for only four percent of the preferred brands.

This is perhaps not surprising, because youth access to cigars is already comprehensively regulated in all states. All states bar minors from purchasing or possessing cigars, and the FDA-audited compliance rate of retail tobacco shops is an impressive 95.7 percent.

Premium Cigar Consumption Patterns

The vast majority of premium cigar consumers are only occasional users (one cigar per day or less). In fact, Monograph 9 emphasizes the fact that few people are "regular" cigar smokers. As stated in Monograph 9:

> Most cigarette smokers smoke every day. In contrast, as many as three-quarters of cigar smokers smoke only occasionally, and some may only smoke a few cigars per year. This difference in frequency of exposure translates into lower disease risk.

Monograph 9 at iii. The 2010 Surgeon General's Report, How Tobacco Smoke Causes Disease, also notes that most cigar consumers smoke less than one cigar daily.

Premium cigar smokers smoke at an even lower frequency than reported in Monograph 9 for all cigar smokers. In May 2009, *Cigar Aficionado* magazine conducted a survey of premium cigar consumption patterns. According to that survey, 43 percent smoke two cigars or less per week and 36 percent smoke three to six cigars per week. Thus, the *Cigar Aficionado* survey

found that almost 80 percent of premium cigar consumers smoke less than one cigar per day, demonstrating that premium cigar smokers consume even less than the typical infrequent cigar smoker discussed in Monograph 9. Infrequent cigar smokers by definition cannot be addicted. As Monograph 9 notes, "there would be little basis to expect that substantial levels of physical dependence would be observed in people who rarely smoked on two or more consecutive days." Monograph 9 at 190.

A recent report from the Centers for Disease Control shows that daily consumption of premium cigars is even lower than reported in Monograph 9 or the *Cigar Aficionado* survey cited above. According to this report, "[a]mong cigar smokers who usually smoked premium cigars, 3.3 percent reported 'every day' use, 25.6 percent reported 'some day' use, and 71.2 percent reported use 'rarely.'" Morbidity and Mortality Weekly Report "Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012–2013"August 1, 2014 / 63(30);650-654. Thus, according to the federal government's own statistics, 96.7 percent of premium cigar smokers do not smoke them every day.[2]

Not only do premium cigar smokers consume the products less frequently, which translates into lower disease risk, they also consume the products differently, which also substantially lowers disease risk. The same *Cigar Aficionado* survey referenced above found that 86percent of premium cigar consumers do not inhale at all, and certainly do not inhale deeply. Monograph 9 similarly acknowledges that most cigar smokers do not inhale. It reported that approximately 80 percent of primary cigar smokers do not inhale, and only 0.5 percent inhale deeply. (Monograph 9, at Chapter 4, Figure 1).

The fact that premium cigars are not inhaled is also demonstrated by studies showing that nicotine is effectively absent in cigar smokers. Cigars deliver very little nicotine, largely because the smoke is not inhaled. The major metabolite of nicotine (cotinine) was measured in two recent studies (Rodriguez, J., et al., The association of pipe and cigar use with cotinine levels, lung function, and airflow obstruction: a cross-sectional study. Annals of Internal Medicine, 2010. 152(4): p. 201-10; Funck-Brentano, C., et al., Effects of type of smoking (pipe, cigars or cigarettes) on biological indices of tobacco exposure and toxicity. Lung Cancer, 2006. 54(1): p. 11-18). There may be some nicotine absorbed in the oral cavity, and this could be relevant in cigar smokers who do not inhale, as nicotine absorbed orally will still produce cotinine in body fluids. The presence of cotinine in body fluids is an unequivocal marker of nicotine absorption.

The Rodriguez study examined urine cotinine concentrations in non-smokers, cigar smokers, pipe smokers, and cigarette smokers. There were 47 cigar smokers, of whom "16 subjects denied ever using cigarettes." The median urinary cotinine concentration for these 16 subjects was 11 ng/ml, identical to the median for the non-smokers. These biomarker results indicate no nicotine uptake in the cigar group. The median value for cigarette smokers was 430 times higher than the median for cigars. The results from these studies confirm that nicotine absorption (by either the inhalation or oral route) is effectively absent in cigar smokers.

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[2] CRA does not hereby endorse all of the findings in that report. CRA particularly questions that report's claim that almost 20 percent of cigar smokers consume premium cigars, a claim that is entirely at odds with the data discussed above regarding the size of the industry. This claim could be due, in part, to the report's overly-expansive definition of a premium cigar.

Since the data shows little or no absorption of nicotine in cigar smokers (orally or in the lungs), then these smokers cannot be nicotine dependent. Nor do these smokers inhale deeply, if at all. Furthermore, the lack of absorption of nicotine in the cigar smokers probably means that there is minimal absorption of other tobacco smoke components that may be expected to result in toxicity.

Premium Cigar Disease Risk and Mortality

The foregoing discussion of premium cigar consumption and inhalation patterns is important, because those patterns yield disease and mortality rates that are far lower than cigarette and other tobacco consumers, and more akin to non-smokers. The question to be asked is whether the risks of premium cigars are sufficiently high to justify regulating them on par with cigarettes and other tobacco products. The answer is clearly no.[3]

Monograph 9 found that the typical occasional cigar smoker had an "all cause" mortality ratio of 1.02, as compared to a ratio of 1.0 for nonsmokers. (Monograph 9, at Chapter 1, Table 1). These cigar smokers are at no greater risk of any disease, including lung cancer (Monograph 9 at Chapter 4, Table 7), buccal and pharyngeal cancer (Monograph 9 at Chapter 4, Table 11), cancer of the larynx (Monograph 9 at Chapter 4, Table 18), cancer of the esophagus (Monograph 9 at Chapter 4, Table 21), pancreatic cancer (Monograph 9 at Chapter 4, Table 27), coronary heart disease (Monograph 9 at Chapter 4, Table 31), COPD (Monograph 9 at Chapter 4, Table 35), or cerebrovascular disease (Monograph 9 at Chapter 4, Table 39). Likewise, Monograph 9 found that cigar smokers that do not inhale have "all cause" mortality rates very similar to that of nonsmokers (1.04 versus 1.0). (Monograph 9, at Chapter 1, Table 1).

Despite the fact that at least 75 percent of premium cigar smokers are "occasional" smokers, the lowest level of exposure presented in the health risk tables in Monograph 9 is 1-2 cigars per day. Apparently, there is no data for health risks among the majority of cigar smokers, who are "occasional" cigar smokers. As noted above, the vast majority of studies (including Monograph 9) fail to distinguish between cigar types, and there do not appear to be any studies addressing the health risks of premium cigars specifically. However, given their different consumption and inhalation patterns, premium cigars are readily distinguishable from other types of cigars, where use is more frequent and inhalation more likely. It is therefore misleading to generalize about the alleged public health risk of cigars without defining the type of cigar in question. In short, the FDA should not arbitrarily lump all types of cigars together in evaluating the health risks of premium cigars.

Even in studies that do not distinguish among cigar types, the number of cancer cases with cigar smokers is usually very small. Boffetta, P., et al., 1999. Cigar and pipe smoking and lung cancer risk: A multicenter study from Europe. Journal of the National Cancer Institute. 91, 697-701. Some reviews present odds ratios without disclosing that these summary statistics were calculated using very small numbers of cases.

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[3] For more detail on these issues, see the report from Dr. Chris Coggins, "A review of the possible health effects of cigar smoking," attached as Exhibit B.

Quite often the odds ratios are not statistically significant. Shapiro, J. A., et al., 2000. Cigar smoking in men and risk of death from tobacco-related cancers. Journal of the National Cancer Institute. 92, 333-337. This study examined several different cancers in 7,868 former and 7,888 current male cigar smokers. The number of deaths was very small and none of the odds ratios produced for consumptions of one to two cigars per day was statistically significant.

A typical example is EPIC, the European Prospective Investigation into Cancer and Nutrition (1991-1998). This study had 521,457 subjects from ten European countries. Despite this large number, there were only 520 lung cancer cases in exclusive cigarette smokers, 22 in never smokers, and three in exclusive cigar smokers. McCormack, V., et al., 2010. Cigar and pipe smoking and cancer risk in the European Prospective Investigation into Cancer and Nutrition (EPIC). International Journal of Cancer. 127, 2402-2411. The odds ratio was 2.4, but this number is not statistically significant. With respect to "tobacco-related" cancers overall, there were a total of 620 tobacco-related cancers in nonsmokers and 42 cases in exclusive cigar smokers. The resulting odds ratio also is not statistically significant; there was no difference between exclusive cigar smokers and never smokers.

With respect to non-cancer disease, although cigarette smoking is strongly associated with cardiovascular disease and chronic obstructive pulmonary disease, effectively no associations have been noted for smokers of fewer than five cigars per day. Iribarren, C., et al., 1999. Effect of cigar smoking on the risk of cardiovascular disease, chronic obstructive pulmonary disease, and cancer in men. New England Journal of Medicine. 340, 1773-1780. This consumption rate is consistent with, and indeed much lower than the typical premium cigar smoker's consumption. Thus, the typical premium cigar smoker has similar non-cancer disease risk to that of a non-smoker.

An alternative approach to studying individual diseases with low incidence rates is to use "all-cause mortality," which combines death risks from all diseases. In one study with 21,520 subjects and 1,230 deaths, there were no differences between combined mortality from lung cancer, cardiovascular disease ("CVD") and chronic-obstructive puliminary disorder ("COPD") between "exclusive cigar use" and "lifelong non-smoker." Wald, N. J., Watt, H. C., 1997. Prospective study of effect of switching from cigarettes to pipes or cigars on mortality from three smoking related diseases. British Medical Journal. 314, 1860-1863. As discussed above, Monograph 9 had similar findings.

Some references, including Monograph 9, note that cigar risk ratios increase as levels of inhalation increase. This data is presented in Table 4, at page 113 of Monograph 9. However, this data is driven by the highest consumption level of cigars, as presented in Table 3 of Monograph 9. This ignores the clear exposure-response relationship demonstrated in Table 3. Thus, although the risks of inhalation for all cigar smokers are higher, this is not true for all levels of consumption. As shown in Table 3, persons who smoke one to two cigars per day have no increased mortality risk.

Even this level of cigar consumption, which is the lowest category of usage presented in Monograph 9, does not reflect the frequency with which adults enjoy premium cigars. However, even Monograph 9 acknowledges that the vast majority of cigar smokers smoke fewer than 1 cigar per day. In other words, the risks for the 80 percent of cigar smokers who smoke only

"occasionally" must be even less that that presented in Monograph 9 for smokers of one to two cigars per day. However, Monograph 9 never presents data for the largest group of cigar smokers.

Moreover, the comment from Monograph 9 qualifies mortality risk by noting that it applies only to cigar smokers who inhale. Yet Monograph 9 acknowledges elsewhere that most smokers do not inhale, with a corresponding impact on disease risk:

> While almost all cigarette smokers inhale, the majority of cigar smokers do not. . . . This reduction in inhalation is one of the reasons for the difference in disease risks between cigarette and cigar smokers.

Monograph 9, Preface, at ii (emphasis added).

Taking into account actual inhalation patterns, Table 4 on page 113 of Monograph 9 presents risks by inhalation level. It shows that for non-inhalers, there is no increased risk of death. Taken together, Tables 3 and 4 of Monograph 9 show that the vast majority of cigar smokers (one or two per day or fewer and/or those who do not inhale) are at no increased risk whatsoever.

Turning to specific disease risks identified in the FDA's proposed regulations, premium cigar smokers have no increased risk of lung cancer. Lung cancer risks are depicted on Tables 7 and 8 on pages 120-121 of Monograph 9. As with the mortality data discussed above, Table 7 shows that the typical infrequent cigar smoker (one to two cigars per day) is not exposed to any increased risk of lung cancer. Table 8 shows that cigar smokers who inhale slightly are at no increased risk of lung cancer. Thus, premium cigar smokers, who likely smoke even fewer than one to two cigar per day, and who do not inhale, have no increased risk of lung cancer.

With respect to oral and pharyngeal cancers, Monograph 9 tells a similar story. These risks are depicted in Tables 11-14 on pages 125-127 of Monograph 9. Again, these tables exhibit a clear exposure-response relationship. However, for the typical infrequent cigar smoker, there is no increased risk of oral ("buccal") or pharyngeal cancer.

The data in Monograph 9 suffers from the additional defects in they are very old (the oldest being a study from 1920), does not differentiate primary from secondary cigars smokers, often combines cigar smokers with pipe smokers, and has very small numbers of studies examined. There does not appear to be any definitive epidemiology data in the published literature on rates of oral, esophageal and laryngeal cancer in primary cigar smokers.[4]

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[4] The proposed regulations refer to levels of harmful and potentially harmful components ("HPHCs"), including tobacco specific nitrosamines ("TSNAs"), in cigar tobacco and smoke. One of the very few references to HPHC concentrations is to work from a conference organized by the American Cancer Society in 1998. Baker, F., S. R. Ainsworth, J. T. Dye, C. Crammer, M. J. Thun, D. Hoffmann, J. L. Repace, J. E. Henningfield, J. Slade, J. Pinney, T. Shanks, D. M. Burns, G. N. Connolly and D. R. Shopland (2000). "Health risks associated with cigar smoking." Journal of the American Medical Association 284(6): 735-740. Claims are made regarding TSNAs without any reference to methods used, limits of detection, or where the work was

The Appropriate Definition of a Premium Cigar

CRA again commends the FDA for "Option 2" proposal as it pertains to premium cigars, and agrees with each element of the proposed definition of premium cigar, with the exception of the price point.[5] Having established that premium cigar consumers' unique age demographics, consumption and usage patterns, and disease and mortality risks compel treating premium cigars distinctly from other tobacco products, the task becomes how to appropriately define a premium cigar for purposes of an exemption from FDA regulation. It is important that such a definition not be under-inclusive, such that it fails to encompass those cigars that are truly distinguishable from other tobacco products, nor over-inclusive, such that tobacco control advocates suggest it would be susceptible to manipulation by purveyors of mass-market cigars that may have higher youth usage rates and/or adverse health impacts.[6]

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performed. No mention is made of how these very low concentrations could be extrapolated to TSNA concentrations in cigar smoke. Other than this solitary citation, an extensive review of the literature on HPHCs (including TSNAs) in cigar smoke has revealed very little information. This lack of information may well be due to the large range of physical sizes of cigar products, the lack of a commonly-accepted smoking regime (unlike the situation for cigarettes), and the lack of well-defined analytical procedures. The paucity of information also may be due to the generally-accepted minimal risks for cigar smoking.

[5] The House Appropriations Committee has similarly noted its approval:

> The Committee is encouraged that FDA has provided options as a way forward on distinguishing between premium cigars and other tobacco products in its recently proposed rule . . . . [T]he Committee notes that FDA is considering excluding premium cigars from the scope of this proposed rule through Option 2. The Committee believes this could be a viable solution, given that the [Tobacco Control Act] makes little mention of cigars throughout the legislation, and there is even less evidence that Congress intended to focus on this unique subset of premium cigars. The Committee notes that premium cigars are shown to be distinct from other tobacco products in their effects on youth initiation, the frequency of their use by youth and young adults, and other such behavioral and economic factors.

H.R. Rep. No. 113-__, at 60, http://appropriations.house.gov/uploadedfiles/hrpt-113-hr-fy2015-agriculture.pdf.

[6] As the FDA is well aware, CRA has long supported the Traditional Cigar Manufacturing and Small Business Jobs Preservation Act and that bill's definition for purposes of an exemption of premium cigars from the FDA's authority. That bill's definition of a "traditional large and premium cigar" has many similarities with the definition in the proposed regulations that would exempt a defined category of cigars from FDA regulation. One could very credibly argue that an otherwise premium cigar made with 1930s-vintage machinery is functionally identical to a hand-rolled cigar from a public health perspective.

CRA accepts the FDA's proposed definition, without the $10 price qualifier contained in the "Option 2" definition of a "covered cigar." We first offer a justification for the elements of the proposed definition with which we agree:

- The Option 2 definition requires the use of 100 percent or whole leaf tobacco. We agree with this. This requirement distinguishes the total unadulterated leaf used in premium cigars from the homogenized wrappers (made of upwards of 33 percent cellulose pulp and the remainder tobacco) frequently used in mass-market products. Leaf tobacco is more expensive than homogenized tobacco wrapper and cannot be used on high-speed machines.

- The Option 2 definition requires 100 percent leaf tobacco binder. We agree with this, as it also distinguishes premium cigars from mass-produced products.

- The Option 2 definition requires primarily long filler tobacco. We agree with this qualification as it further clarifies the distinction between hand-rolled premium cigars and mass-market cigars.

- The Option 2 definition requires manually combining the wrapper, filler and binder. We agree with this, as it distinguishes hand-made products from those made with high-speed machinery.

- The Option 2 definition prohibits the use of a filter, tip or non-tobacco mouthpiece. We agree with this, as it distinguishes premium cigars from many machine-made, mass-market cigars. No premium, hand-rolled cigars contain a filter, tip or non-tobacco mouthpiece. A filter also is likely to result in higher inhalation rates, which increases disease risk.

- The Option 2 definition prohibits characterizing flavors except all natural tobacco. We agree that a premium cigar should not have a characterizing flavor other than tobacco. However, we would like further clarification to define the term "characterizing flavor."

- Finally, the Option 2 definition requires a weight of more than six pounds per 1000 units. We agree with this. Federal law already establishes weight as a way of distinguishing among cigar types. See 26 U.S.C. § 5701. The proposed weight qualifier doubles the weight necessary to qualify as a "large cigar" for purposes of federal tobacco excise taxation, and eliminates the possibility of evasion through minor product changes. Increasing the weight of a cigar generally increases the price by roughly doubling the amount of raw material used in the product.

We disagree, however, with the proposed $10 retail price qualifier for several reasons. Because of the other elements of a definition of a premium cigar discussed above, premium cigars are more expensive than other cigars that are the FDA's apparent concern and thus a price quantifier is not justified. Leaf wrapper is substantially more expensive than reconstituted homogenized tobacco paper. Doubling the weight of the cigars roughly doubles the necessary raw materials, which necessarily increases the price. Finally, the manual nature of

producing premium cigars substantially increases the cost versus products made with high-speed machinery. These other elements of the definition can therefore be thought of as a self-executing price qualifier, necessarily dictating significantly higher price points than other tobacco products.

Second, the $10 limitation excludes the vast majority of cigars that otherwise qualify as "premium" and that, based on their relative health impacts and lack of youth appeal, are readily differentiated from other tobacco products. Indeed, the FDA concedes this point. The proposed regulations' Regulatory Flexibility Analysis indicates that, on one "well-known Internet site[]," 87 percent of handmade cigars fall below $10. Our own research confirms this. Seventy percent of the premium cigars rated by *Cigar Aficionado* magazine in 2013 fell below the $10 threshold. *Cigar Aficionado*, Speak Up, http://www.cigaraficionado.com/blogs/show/id/17611.

Third, any retail price qualifier is unfeasible. Cigar manufacturers and importers – the entities that would bear the brunt of FDA compliance obligations – do not control retail prices; retailers control retail prices. This is both a market reality and a function of antitrust constraints on resale price maintenance. See Leegin Creative Leather Products v. PSKS, Inc., 551 U.S. 877 (2007). Yet manufacturers and importers must determine at the outset whether their products are subject to FDA oversight for a variety of purposes, including product registration and premarket review. This is a practical impossibility, however, if an independent retailer's pricing decisions dictate a product's regulatory status. Furthermore, FDA officials have reportedly advised congressional staff that it has not yet determined an enforcement mechanism for this element.

The proposed price qualifier also ignores the impact of geography and varying sales channels. Sales on the Internet, where prices are generally lower, are an obvious example. Varying state excise tax rates, which necessarily impact the retail price, is another example. Those taxes range from three to 40.5 cents per ten cigars (Alabama) to nothing (Florida) to ten percent of the manufacturer's price (Missouri) to 75 percent of the wholesale price (New York) to 95 percent of the wholesale price (Washington). Federation of Tax Administrators, State Taxes on Other Tobacco Products, http://www.taxadmin.org/fta/rate/otp.pdf. Thus, the identical cigar has dramatically different retail prices depending on where it is sold. It is unclear how this would impact a manufacturer's compliance obligations. Is the retail price qualifier judged by the lowest retail price, the highest retail price, or some suggested retail price? Irrespective of how "retail price" is determined, the outcome is arbitrary. The proposed qualifier also does not address the impact of individual retailer decisions to discount prices. Again, the FDA appears to be unable to articulate a feasible mechanism as congressional staff have requested.

Finally, the $10 qualifier appears to lack any basis. Other than citing examples from just two websites (among the hundreds of websites that sell premium cigars) and a five-year-old "cigar cyclopedia," it does not appear that the FDA comprehensively researched premium cigar retail prices. Nor does the FDA offer any public health justification for the price qualifier. The FDA does not assert, for example, that cigars priced $10 and above have different youth appeal

or health impacts versus those priced below $10.[7] Moreover, there is no precedent with the FDA for promulgating a regulation with an economic quantifier.

Comments on Specific Aspects of the FDA's Proposal

For the foregoing reasons, we do not believe that premium cigars should be subject to any form of FDA regulation. Turning to the specifics of the FDA's proposal, we are most concerned with the following requirements:

"New Tobacco Product" Review

A literal application of FDA's new tobacco product authority to premium cigars could prohibit the sale of new or altered products, which would constitute an impermissible ban on premium cigars. See 21 U.S.C. § 387g(d)(3)(A) (prohibiting the FDA from banning any type of tobacco product). Section 910 of the Tobacco Control Act defines a "new tobacco product" as one that was not commercially marketed in the United States as of February 15, 2007, or that has been changed in any way since February 15, 2007. 21 U.S.C. 387j(a)(2)(A). Generally, new tobacco products cannot be commercially marketed without FDA approval.

If applied literally, any premium cigar introduced or changed since February 2007 could not be sold without FDA approval. As discussed above, because of the unique nature of premium cigars, this would impact all – or virtually all – premium cigars. Each and every one of these artisanal, hand-made product could be regarded as "new." Premium cigars are thus like fine wines – no two are exactly alike.

How, for example, does one assess whether individual hand-rollers are making cigars with the exact same specifications, whether individual cigar bunchers are using the exact same filler tobacco, or whether individual rollers are using the exact same tobacco leaves as wrappers – particularly as tobacco crops vary from year to year due to temperature changes, the amount of rainfall, and the amount of sunlight? When the framers of the Tobacco Control Act established premarket review requirements for mass-produced, homogenous products like cigarettes, they could not have possibly contemplated applying those requirements to individually-produced products, where each one could be sufficiently different to render them "new tobacco products." It does not appear that the FDA considered any of these issues in drafting the proposed regulations.[8]

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[7] It also is unclear how the FDA would enforce any price qualifier given the legal constraints on the FDA's ability to collect financial data, including pricing data. See 21 U.S.C. § 374(a).

[8] Another stark example of the folly of applying premarket review requirements to premium cigars is the example of individual hand-rollers of premium cigars who sell what they roll directly to retailers or consumers. There are countless of these individuals across the country, all of whom would be considered "tobacco product manufacturers" subject to the FDA's requirements. See 21 U.S.C. § 387(20) (defining a "tobacco product manufacturer" as anyone who "manufactures, fabricates, assembles, processes, or labels a tobacco product").

Premarket review also would uniquely impact premium cigar manufacturers because new product releases and other "limited editions" and "special releases" are particularly important in this industry. As discussed above, cigar consumers are not brand loyal like cigarette consumers; they often buy many different brands even in one visit to their local cigar shop. Manufacturers, therefore, routinely introduce new products to maintain consumer interest. Manufacturers also routinely introduce small-batch "special releases" consisting of perhaps a few hundred boxes. This would be economically infeasible if manufacturers were first required to spend countless hours obtaining premarket approval for just a few cigars.

In addition, premium cigars often have minor variations intended to alter the taste or aroma of the new product, including using tobaccos from different regions or seed varieties to create different taste profiles. Even brands that have been on the market before February 2007 would be considered new products because of various changes to the products' composition, as premium cigar manufacturers seek to maintain consistency in product quality, taste, etc. in the face of sometimes significant changes in the climate, soil, etc. from one year to the next. Other tobacco product manufacturers do not face these substantial hurdles.

The premium cigar industry's burden is compounded considering the FDA's estimate of 5,000 hours to complete just one premarket tobacco application. This level of time and effort, whether undertaken by company employees or outside consultants, is simply unsustainable for the typical manufacturer in this industry. We also believe that the FDA has vastly underestimated the number of premium cigar products that will be subject to premarket review, for the reasons discussed above.

All of these disproportionately burdensome requirements must be viewed through the prism of the FDA's already substantial premarket review workload. According to the FDA's website, of the thousands of premarket review requests – premarket tobacco applications, requests for substantial equivalence and requests for exemption from substantial equivalence – submitted since approximately March 2011, the FDA has acted on less than 150 and approved just 71 (with the majority of these approved in the last few weeks). Many of these premarket review requests have languished for over three years.

It is difficult to imagine adding the thousands of products from the premium cigar industry to this already significant backlog. The typical premium cigar manufacturer may have over one hundred unique SKUs, and typically will turn over about 15 percent of those SKUs in any given year. Each of these changes would trigger new tobacco product requirements.

Our data indicates there are at least 10,000 and maybe as many as 20,000 unique SKUs in the United States, which would add to the FDA's already overwhelming workload in evaluating

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Theoretically, each one of these individually-produced cigars, which are often tailored to individual consumers' tastes, would be subject to a time-consuming and expensive approval process before it could be sold. It is apparent that premarket approval requirements would eviscerate this segment of the industry, which consists entirely of small "mom and pop" businesses.

new product applications. If the FDA has only been able to evaluate a small fraction of the more than 3,500 applications it has received since March 2011, how could FDA possibly accommodate the workload generated by thousands of additional new product applications from the premium cigar industry? We estimate that the premium hand rolled cigar category alone could easily generate numbers in excess of 10,000 applications. And since products generally cannot be introduced or changed until the FDA acts, manufacturers and consumers will suffer due to the FDA's apparent inability to manage its workload.[9] Moreover, consider that the FDA Center for Tobacco Products' budget is set by statute and its resources are limited. Delays for approvals can thus be expected to skyrocket.

Warning Labels

The regulations propose a number of warning labels for cigars. The warning label requirement would be disproportionately expensive for the premium cigar industry, a fact that the FDA recognizes. Premium cigars routinely come packaged in ornate boxes, which are part and parcel of the consumer buying experience, and an integral part of cigar manufacturers' marketing. Covering the upper 30 percent of these boxes not only would negatively impact this aspect of the industry, it would impose substantially higher incremental costs for premium cigar manufacturers.

We particularly object to the size requirement. The FDA offers no rationale for the necessity of a warning covering almost one-third of a cigar box and one-fifth of advertising. Indeed, the FDA concedes that it lacks reliable evidence of the effect of warning labels on cigar consumers. In light of this lack of evidence, the FDA has no basis to compel such large warnings.

More fundamentally, we take issue with the proposed warning labels due to their lack of a sound scientific basis. As discussed above, based on their different consumption rates and inhalation patterns, premium cigar consumers have health profiles similar to those of non-smokers. Premium cigars that meet the criteria for the proposed Option 2 definition should therefore not be subject to warning labels.

With respect to the specific warnings proposed by the FDA, we note the following:

- ***"Warning 1. Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale."*** We disagree with the rationale provided by FDA for this warning, which depends almost exclusively on Monograph 9, which (as discussed above) does not distinguish among cigar types. In particular, we disagree with the statement on "consumers' widely held belief that cigars are safe products if users do not inhale the smoke." A modern view would be that if there is no exposure to the smoke, then increased risks of disease would be very unlikely. This view is borne out by experimental data showing minimal toxicity since cigar smokers do not inhale.

[9] Although the proposed regulations contemplate a two-year grace period after the regulations take effect, during which new products can be provisionally introduced, this only delays the problem, and perhaps magnifies it, since the relevant comparisons must be made to products sold in 2007.

Rodriguez, J., R. Jiang, W. C. Johnson, B. A. MacKenzie, L. J. Smith and R. G. Barr (2010). "The association of pipe and cigar use with cotinine levels, lung function, and airflow obstruction: a cross-sectional study." Annals of Internal Medicine 152(4): 201-210; Funck-Brentano, C., M. Raphael, M. Lafontaine, J. P. Arnould, C. Verstuyft, M. Lebot, D. Costagliola and R. Roussel (2006). "Effects of type of smoking (pipe, cigars or cigarettes) on biological indices of tobacco exposure and toxicity." Lung Cancer 54(1): 11-18.

- ***"Warning 2. Cigar smoking can cause lung cancer and heart disease."*** The rationale for this warning similarly depends on Monograph 9, with all of its infirmities. The rationale is that the epidemiological data for smokers of at least five cigars per day shows risks for lung cancer that are similar to pack a day cigarette smokers. A similar statement is made for cardiovascular disease. The modern view would be that the numbers of people who smoke at least five premium cigars per day is exceedingly small, and that rate of consumption is far higher than the typical occasional smoker.

- ***"Warning 3. Cigars are not a safe alternative to cigarettes."*** Cigarettes are clearly a very risky product but it is clear that cigars are very much less so. As discussed above, the evidence shows that the typical premium cigar smoker has relatively minor risks.

- ***"Warning 4. Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers."*** The scientific evidence disagrees strongly with the claim that "secondhand smoke causes premature death and disease in youth and in adults who do not smoke." The epidemiological links between "being married to a smoker" and increased disease (the basis for the FDA statement) are tenuous at best. It is axiomatic that on a per stick basis cigars can produce larger amounts of environmental tobacco smoke than do cigarettes, but the statement in the regulation (from Monograph 9) on "exposing household members to a considerable involuntary health risk" is simply not accurate.

- ***"Warning 5. Tobacco use increases the risk of infertility, stillbirth, and low birth weight."*** We agree that there do not appear to be studies specifically linking cigars to these reproductive effects, and so the warning should not be used. Anecdotally, significant use of cigars by pregnant women would appear implausible. We are unsure about the FDA statement that cigar smoke is similar to cigarette smoke, since there are very few recent studies that describe the chemistry of cigar smoke.

- ***"New warning. This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."*** This warning is superfluous to the cigar category, since there is minimal exposure to the nicotine, as a result of the absence of inhalation. Rodriguez, J., R. Jiang, W. C. Johnson, B. A. MacKenzie, L. J. Smith and R. G. Barr (2010). "The association of pipe and cigar use with cotinine levels, lung function, and airflow obstruction: a cross-sectional study." Annals of Internal Medicine 152(4): 201-210; Funck-Brentano, C., M. Raphael, M. Lafontaine, J. P. Arnould, C. Verstuyft, M. Lebot, D. Costagliola and R. Roussel (2006). "Effects of type of smoking (pipe, cigars or cigarettes) on biological indices of tobacco exposure and toxicity." Lung Cancer 54(1):

11-18. Consequently, premium cigar smokers have not been reported to show signs of addiction.

In sum, when applied to premium cigars, the proposed warnings lack a sound evidentiary basis. As such they are highly amenable to constitutional challenge on grounds similar to those in R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205 (D.C. Cir. 2012), in which the court found that the FDA's proposed cigarette warning labels violated the First Amendment to the U.S. Constitution.

Testing

It is not uncommon for premium cigar manufacturers to have more than one hundred different products distinguished by brand name, type of tobacco and/or size. Product composition, including nicotine content, will vary naturally every season, and even within a season due to natural changes in soil, rainfall, sun and other environmental factors. Unlike manufacturers of other tobacco products, premium cigar manufacturers do not add hundreds of chemicals to the tobacco - it is used in its natural state after being cured and aged. Under the FDA's application of the Tobacco Control Act's testing requirements, each and every one of these products would need to be tested for harmful and potentially harmful constituents ("HPHCs").

Testing for HPHCs would therefore be disproportionately costly for premium cigar manufacturers and importers, with costs potentially exceeding a company's entire payroll. Alternatively premium cigar manufacturers would be forced to eliminate brands. The proposed regulations acknowledge that the premium cigar industry has a very high number of low-volume products. It makes little sense to introduce a special release of a few hundred boxes, with testing costs likely exceeding $10,000 per SKU.

Moreover, testing of premium cigars offers with no tangible public health benefit. As discussed above, in assessing premium cigars' health impacts, one must take into account actual consumption patterns. Reporting levels of HPHCs, without taking into account how the products are actually used, would present a misleading picture of the products' purported risks.

It is not even clear how the FDA would implement testing requirements for premium cigars. Presently there is no accepted regime for premium cigar testing, which is perhaps not surprising given the products' many different shapes and sizes. And any testing regime would need to account for the fact that, unlike cigarette smokers, premium cigar smokers do not inhale.

We are particularly concerned about the impact of testing requirements on the premarket review process. The FDA has indicated that it generally requires HPHC testing for premarket approvals. Yet, there is no established mechanism for testing cigars at this time. And with premarket review submissions due two years after the regulations' effective date, and testing not required until three years after the regulations' effective date, it is not clear how premium cigar manufacturers could possibly comply with the testing requirement as part of premarket review submissions.

Sampling

The regulations propose to ban cigar sampling. Sampling is critically important for premium cigar manufacturers, which frequently introduce new products and at much higher price points. Adult consumers should be permitted to try an expensive new product before they buy it. Moreover, unlike cigarette consumers, who are exceptionally brand loyal, premium cigar consumers have little brand loyalty. Sampling events are a useful way to introduce consumers to new brands and varieties.

The stated rationale for the sampling ban for cigarettes is youth access, but again there is no evidence that minors consume premium cigars in significant quantities, or that sampling is an avenue to youth access. Moreover, premium cigar retailers already enforce strict minor access laws with established age verification procedures that abide with laws present in every jurisdiction in the United States. Sampling of premium cigars occurs in a controlled environment – adult-only smoke shops – where the tobacconist can conduct appropriate age verification.

Finally, banning samples of premium cigars, while permitting samples of smokeless tobacco, would be arbitrary. The regulations issued pursuant to the Tobacco Control Act bar samples of cigarettes, yet permit them in smokeless tobacco. Given the utter lack of youth consumption issues with premium cigars, it makes no sense to prohibit samples, yet permit samples of products with demonstrably higher youth appeal.

The Regulations' Economic Impact

Compared to cigarettes and other tobacco products, premium cigars represent a miniscule fraction of the market. Premium cigars comprise less than one tenth of a percent of the tobacco market, and less than three percent of the cigar market. Moreover, compared to cigarettes and other tobacco products, premium cigars have substantially lower – and for the typical consumer non-existent – risks. Whether on an economic basis, or on a public health basis, premium cigars pose an infinitesimally small "risk." Clearly, FDA's scarce resources should be focused on more significant public health issues, particularly when there is no evidence to suggest that premium cigars pose a risk to the public health.

Yet the regulations' economic impact on the industry would be dramatic. Industry research shows there are more than 2,000 brick and mortar retail stores that employ on average of four to five full-time and part-time employees. When you consider the jobs up and down the premium cigar supply chain, you arrive at an estimate between 10,000-20,000 jobs that would be negatively impacted by the proposed regulations. By way of example, the 2009 CHIPRA federal excise tax increase was directly responsible for the loss of 500 U.S. jobs in the Tampa cigar community. This is yet another indication that premium cigars lack the regulatory/tax elasticity for survival that mass market products appear to possess. In this regard, the premium cigar industry would be subject to "regulatory capture" at the hands of the major cigarette companies,

whose past marketing conduct serves as the major underlying rationale for the Tobacco Control Act.[10]

The premium cigar category is estimated to be approximately $500 million. The potential impact of over regulation would be well over $100 million dollars and thus considered significant under Executive Order 12866. The cigar producing nations that include the Dominican Republic, Honduras, and Nicaragua alone account for 350,000 jobs. Not only would there be a devastating job loss in the Caribbean Basin (which would have a negative result on trade), but there could be unintended consequences that create domestic security concerns. These have been well expressed by the respective embassy delegations of cigar producing nations to the federal government. The United States may also be subject to retaliatory trade actions under relevant international free trade agreements.

The following are issues that the FDA's economic impact analysis failed to consider, but that should be considered, before the FDA issues any final regulations:

- The economic impact on remaining communities which have cigar factories in the United States: National Cigar Co. in Frankfort, Indiana and their distribution facility in South Windsor, Connecticut and J.C. Newman Cigar Co. in Tampa, Florida.

- The economic impact on the City of New Orleans and the City of Las Vegas, due to the rotation of the national cigar trade show to those cities. The Las Vegas (as well as New York City) assessment needs to include the impact of hosting the Cigar Aficionado Big Smoke for the last 20 years, and with implications for future such events.

- The New Orleans assessment would need to include impact on the production facility of The Cigar Factory, a manufacturer of boutique cigars in the French Quarter District, and a special assessment on the role of tourism impact with the retail premium cigar enterprises, in a post-Katrina New Orleans.

- The economic impact on the State of Florida, given the location of over 45 cigar corporate headquarters operations in the state, industry use of the Ports of Miami, Tampa, and Ft. Lauderdale, distribution and support services, boutique cigar production in the Little Havana community of Miami, and over 300 retail establishments. Impact assessment also needs to include implications for the designated National Historic District of Ybor City, which has a network of boutique cigar production enterprises.

- The economic impact on the primary production nations of Honduras, Nicaragua and the Dominican Republic, and the over 350,000 estimated jobs in the agricultural, craftsman, production, support services and distribution sectors. Implications for import/export relations, impact on foreign debt commitments due to the reliance on premium cigar production, and associated international trade implications, have yet to be assessed.

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[10] Additional information regarding the impact of the proposed regulations on the premium cigar industry is included in Exhibit C, which includes letters from various localities, Chambers of Commerce and industry associations that would be impacted by the proposed regulations.

- The economic impact on cigar tobacco growers in Cameroon and the Central Africa Republic, which produce prized cigar wrapper leaves, with an estimated 3,000 agricultural jobs in each of these African nations.

- The economic impact on cigar tobacco growers in Ecuador, Brazil, Columbia, Puerto Rico, Costa Rica, Peru, Panama, Indonesia, Cameroon, Central Africa Republic, and Mexico as well as production facilities in Mexico.

- The community economic impact on over 2,000 retail stores in the United States, for which over 70 percent of their core sales is premium cigars.

- The economic impact on three boutique cigar production companies located in Louisville, Lawrenceburg and Pikeville, Kentucky; and four boutique cigar production companies located in New Jersey (La Hoja Cigars, Reinado Cigars, Moya Ruiz Cigars, and Tony Santana Cigar Rolling Co.). New Jersey is also the corporate headquarters for Nat Sherman and JR Cigars, two of the largest companies in the premium cigar sector.

- The economic impact on over 44 small batch manufacturers in the newly organized American Boutique Cigar Manufacturers Association, located throughout the United States.

- The economic impact on approximately 100 family farms in the Connecticut River Valley of Massachusetts and Connecticut, that have over 5,000 seasonal workers, with an estimated $100 million crop, that is solely dependent on the premium cigar market, and associated implications for the farm machinery, farm credit, fertilizer, fuel, farm supply and repair enterprises in the Connecticut River Valley.

- The economic impact on the Commonwealth of Pennsylvania, given that over 50 percent of the nation's premium cigars are distributed through Pennsylvania, as well as a significant tourism impact (built around samples of premium cigars) that annually brings more than 10,000 visitors to Pennsylvania, exclusively for cigar themed festivals. In addition to these factors, Pennsylvania, like Connecticut, grows prized broadleaf cigar wrapper, hence having implications for Pennsylvania's farming community.

- The national security implications of regulating premium cigars, within the Latin American region where premium cigar production in concentrated. Any regulatory measures that jeopardizes employment in the region, by impacting production, could result in adverse internal and external political climate changes, that work against American national interests, and overall economic and political stability in the region.

The premium cigar industry in the Dominican Republic, Honduras, and Nicaragua provides over 350,000 direct jobs in the Caribbean Basin. The industry provides families with living wages, health care and education. If one considers the families reliant on the premium cigar industry for income, the number of people who would be impacted by FDA regulation of premium cigars explodes to over 1,000,000 individuals (including thousands of jobs employing Haitian farm workers in the Dominican Republic). The negative impact and unintended consequences of this regulation could contribute to the type of economic instability the region

has experienced in recent history. Moreover, the economic impact of FDA regulation of the premium cigar industry could implicate other areas of national interest, such as America's national security interests. The possible extraterritorial effects of FDA regulation on the domestic economies and societies of countries in the Caribbean Basin is an issue that warrants further analysis.

Further, the user fees that the FDA would impose on premium cigar manufacturers or importers erects a barrier to the importation of the roughly 260 million premium cigars that are currently imported from our Caribbean Basin partners. Consequently, the user fee would place a burden on commerce between the United States and the Caribbean Basin countries, thereby violating the spirit of the Dominican Republic–Central America Free Trade Agreement ("DR–CAFTA").

A central theme that orbited the signing of DR-CAFTA was that to keep our economy growing and creating jobs, we need to open markets for American products overseas. We understood at the time that strengthening our economic ties with our democratic neighbors is vital to America's economic and national security interests. Furthermore, we understood that by strengthening ties with democracies in our hemisphere, we were advancing the stability that comes from freedom. The purpose of DR–CAFTA was to facilitate trade between the United States and its Caribbean neighbors and the imposition of a user fee on imported cigars undermines this goal.

The FDA's Preliminary Regulatory Impact Analysis is Deficient[11]

Executive Order ("EO") 12866, Regulatory Planning and Review, was promulgated to improve the regulatory system of the United States:

> The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

The EO describes a regulatory philosophy the adherence to which ensures better regulations:

> Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health

[11] These issues are also addressed in the report of Lawrence G. Buc, entitled "The FDA's Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis are Deficient and Provide No Support for Regulating Premium Cigars," attached as Exhibit D.

> and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

By the terms of the EO, the FDA's Regulatory Impact Analysis ("RIA") is deficient. It does not show a compelling public need for regulating premium cigars. Further, it does not adequately assess the costs, benefits, and distributional effects of regulating. Finally, it fails to show that the FDA even calculated net benefits of its proposal, much less maximizes them as required. In summary, the RIA does not support the proposed regulations. We provide details below.

First, FDA has not demonstrated a compelling public need for regulation of premium cigars as tobacco products based on general public health considerations or on youth access issues. These issues are discussed in greater detail in CRA's previous comments. In his report to CRA, "A review of the possible health effects of cigar smoking," Dr. Coggins shows that the scientific data and literature refute the FDA's contention that smoking premium cigars poses health risks comparable to other tobacco products. He summarizes the evidence on health risks from cigars: "...lifelong smokers of cigars tend to have risks for smoking-related disease very close to those reported for non-smokers." Coggins at 2. Further, the FDA also recognizes that state regulations prohibit the sale of tobacco products to minors, although the definition of tobacco products varies across states. RIA at 13. To further this point, the FDA to date has conducted 312,286 compliance check inspections, of currently regulated tobacco products, at the retail level. An analysis of these checks shows that the current compliance rate at the retail level, as it relates to violations involving minors, on currently regulated tobacco products is equal to 95.7 percent compliance with federal laws and regulations. Clearly, this high level of compliance demonstrates that retailers of currently regulated tobacco products take seriously their role in preventing the usage of tobacco products by underage individuals. Therefore, given the unique nature of premium cigars, coupled with the fact that premium cigar retailers apply strict standards with regards to age requirements for entering their establishment, there is no compelling public need or reason for extending regulatory authority to premium cigars.

Second, lacking quantified measures of benefits, FDA has not selected and cannot select a regulatory approach that maximizes net benefits as required by the EO. As the RIA states:

> The direct benefits of making each of the proposed deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify without additional data, and we cannot predict the size of the benefits at this time. RIA at 7.

FDA goes on to discuss the mechanisms for producing the benefits they can only hypothesize but cannot demonstrate:

> FDA anticipates, however, that the largest benefit of the proposed provisions would be the improvements in health and life expectancy resulting from reductions in the use of combustible tobacco products deemed under this proposed rule. Most notable, the required warning labels on product packaging and advertising can more effectively inform potential users of the health risks of cigars and the addictiveness of cigars and other covered tobacco products, cigarette tobacco, and roll-your-own tobacco. Consumers may respond to this information by reducing their use of these products or engaging in compensating health behaviors. RIA at 13.

However, with respect to these hypothesized benefits the agency forthrightly admits:

> We lack sufficient information on consumers of cigars and other combustible products to make direct inferences of the welfare gains from decreased use but because cigarettes are the closest products to the products covered by the proposed rule, we can make inferences about the welfare effects associated with reducing the use of cigarettes. We acknowledge, however, that the effect of using other tobacco products may differ from the effects of smoking cigarettes; some may have very similar effect to cigarettes, while other may differ substantially. RIA at 14.

These paragraphs show that the FDA's benefits analysis is enormously incomplete, speculative and incapable of supporting the proposed regulations with respect to premium cigars. It does not comply with the EO.

Further, as FDA recognizes, the magnitude of any benefits from the proposed regulation on premium cigars depend not only on the physical relationship between reductions in premium cigar smoking and health, uncertain at best, but also on the relationship between the regulations and consumer and industry behavior in reaction to those benefits. While consumers "may respond to this information by reducing their use of these products or engaging in compensating health behaviors" they also may not or they may do so to a much lesser degree than the FDA would wish. Or, notwithstanding the evidence that shows that smoking premium cigars does not confer health risk, if consumers mistakenly did feel safer with respect to changes in their smoking behavior, they might increase their risks in other arenas. This would be doubly troubling since they could adapt behaviors demonstrably more risky than smoking premium cigars.

The literature has long recognized that people respond to risk changes caused by safety laws and regulations by compensating or homeostatic behavior, a behavior that is equally applicable to health regulations. The academic James Hedlund outlines the issue quite succinctly in a Haddon Memorial Lecture entitled "Risky business: safety regulations, risk compensation, and individual behavior":

> Government regulations and industry practices constrain our behavior in many ways in an attempt to reduce injuries. Safety features are designed into products we use: cars now have airbags; medicine bottles have "childproof" caps. Laws require us to act in a safe manner: we must wear seat belts while driving and hard hats in construction areas. But do these measures influence our behavior in other ways? Risk compensation theory hypothesizes that they do, that we "use up" the additional safety though more risky actions.

After an extensive review of the evidence, Hedlund states:

> Behavioral adaptation and risk compensation clearly occur in some situations. We react to changed conditions; we are famous for not always doing as we are told or as is expected of us. On the other hand, I believe the evidence is overwhelming that every safety law or regulation is not counterbalanced by compensating behavior.
>
> Thus the issue becomes not yes or no, but when and how much. When may compensation occur in response to a safety measure? How likely is it to occur? What are its possible consequences, both direct and indirect?

Hedlund's position with respect to estimating benefits of injury prevention measures is surely applicable to the highly speculative benefits from regulating premium cigars:

> *Don't over-predict benefits.* Many injury prevention measures promise more benefits than they deliver, due to bad science, political pressures, or failure to consider risk compensation or system effects. While calm and realistic benefit estimates are difficult to produce, unduly optimistic predictions will hamper injury prevention efforts in the long run.

Third, the cost analysis in the RIA embodies obvious errors; it also understates the costs of deeming and regulating because it is incomplete with respect to the costs that it quantifies.

With respect to obvious errors, Table 1: Summary of Quantified Costs Over 20 Years appears on page 8 of the RIA. In that table, the Annualized Values at a 7 percent discount rate at the Lower Bound, the Upper Bound, and the Primary for both Options 1 and 2 are larger than their corresponding values at a 3 percent discount rate. These relationships are clearly in error since higher discount rates of necessity produce lower Annualized Values, unless the costs being annualized were incurred in the past or unless for some strange reason the undiscounted values differ before discount rates are applied. Unfortunately, a mistake in something this fundamental raises questions about the entire cost analysis.

The cost analysis is also incomplete as well as erroneous. While it does estimate costs for some of the activities that newly-regulated businesses will have to undertake, it omits others. Most important, there is no estimate of the cost of businesses reading, understanding, and studying the regulations; deciding whether they will exit the market or remain market participants; and developing implementation and compliance plans and approaches if they

remain in the market. There would be considerable cost associated with these activities – they will take a fair amount of time and those performing them are likely to be well compensated. This cost does not appear in the RIA. It is also important to note that this cost is likely to be relatively fixed with respect to the size of the establishment meaning that smaller businesses will incur a larger per-unit costs than larger ones; this disproportionate impact on smaller business will have implications on the distributive effects of the regulations.

FDA itself admits that the cost analysis is incomplete: "We acknowledge that product exit reduces product variety and the range of choices available to consumers, but we do not estimate the value of this loss of consumer choice." No reason appears for this omission. If the analysis hopes to estimate welfare changes, however, it must include values for the important loss of consumer choice.

The analysis also ignores the costs of behavioral changes on the part of newly-regulated entities which will lead to increased costs. Cigar manufacturers and retail operations, like all other businesses, presently use a cost-effective mix of marketing channels that include (1) free samples, an important marketing channel (according to industry sources) for premium cigars which would be precluded by the proposed regulations, and (2) channels like direct mail, internet, and event marketing at retail locations which will not be affected. As generally accepted in the economics of marketing, marketing expenditures are allocated across channels so that the last dollar spent on each channel produces the same dollar value of sales or profit in each. If not, a business could increase its sales or profit by reallocating marketing expenditures across channels until this condition were satisfied. But with free samples precluded by regulation, marketing will switch to permissible ones. The additional marketing in the permissible channels will be less effective than the previous marketing in the now impermissible channel (otherwise the business would have previously increased marketing in these permissible channels) so marketing costs will increase at all levels of sales or profit. And this additional cost has been totally ignored in the RIA. More concretely, two major events in Pennsylvania, attracting over 10,000 participants, are centered on free samples and free samples are widely used by retail shops.

The RIA cost estimate conceptually accounts for the fact that the some foreign producers will exit the US market as a result of these regulations. To operationalize this construct, it assumes that 10 to 50 percent of the products of these foreign producers will not continue to be marketed in the United States (the RIA at page 29 states that 50 to 90 percent will be marketed, the percent not marketed is the complement.) Thus, in estimating total costs for activities, which apply at the product level, the FDA assumes a smaller universe of products than currently exists. But the implications of exit are never really traced in subsequent portions of the analysis.

Fourth, the RIA underestimates unit costs for many activities and consequently underestimates the costs of the regulations. For ingredient listing and for premarket tobacco applications, FDA assumes a labor mix to perform the activity and then applies an occupation-specific unit cost from BLS to develop a unit cost for the activities. The labor mix assumes 30 percent life, physical, and social science occupations; 20 percent architecture and engineering occupations; 30 percent office and administration occupations; and 20 percent legal occupations.

The resulting composite wage is then doubled to account for overheads and yields an hourly labor cost of $66.50. RIA at 31.

This labor cost is understated for three reasons. First, the labor mix for these activities is incorrect. Industry participants state that they believe legal occupations would account for about 40 percent of the time and executive management for about 20 percent of the time. Second, since much of the legal labor is externally sourced, an hourly rate (before overhead) of $42.15 is vastly understated. And executive management hourly rate, before overhead, is about $100 per hour. Third, a factor of only two for overhead is arguably low based on my experience. The correct hourly labor cost easily exceeds $125 per hour and is likely larger.

In addition to the significant pre-market application costs for new products, the proposed health warning requirements will place an additional cost on manufacturers, particularly those that are not today signatories to the FTC Consent Orders. Under Option 1, each manufacturer would need to design five warning versions for each UPC. In the RIA, Tables 29 and 30, page 44, the FDA estimates the cost per UPC for "Coordinated" and "Uncoordinated Changes" and then applies those per UPC estimates to the quantities of each change projected to be required for machine-made cigars, premium cigars and non-premium handmade cigars.

Of particular concern is that all premium cigar UPCs that are owned by companies who are not parties to the FTC Consent Orders will be subject to these costs. As an example, one mainstream premium cigar company, Davidoff of Geneva USA currently reports 1670 UPCs (see Davidoff of Geneva USA Comments), each of which would require the full cost of "Uncoordinated Changes," amounting to anywhere from $10,365,690 on the low side according to FDA ($6,207 per UPC X 1,670 UPCs) to $28,161,210 ($16,863 per UPC X 1,670 UPCs) on the high side. This does not include the ongoing annual administrative and record keeping costs. A cost of this magnitude would result in forcing this manufacturer to eliminate from the market a very high percentage of current UPCs (potentially well in excess of half in order to stay financially viable). This picture would be even more severe for manufacturers with narrower brand portfolios and would cause financial distress across most small to medium size premium cigar manufacturers. Further, although there is no reliable up-to-date source, the total number of UPCs included in the analysis by FDA for premium cigars appears to be significantly understating the actual number in the market and, by extension, so is the total cost of these warning label requirements.[12]

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[12] In a July 2014 report, "An Evaluation of the Costs and Benefits of the Graphic Warning Label Regulation," a group of economists assert that the FDA has underestimated the benefits of graphic warning labels. Although we have not had time to review the report in any detail, we do note that the alleged underestimate of benefits critically depends on asserted improvements in valuing the reductions in health effects from reductions in smoking that would be caused by the graphic warning labels. In his report to CRA, Dr. Coggins refutes the FDA's assertion that smoking premium cigars poses health risks using the best interpretation of the scientific data and literature. Thus, if there are no health improvements, underestimating the benefit of improvements does not lead to an underestimate of benefits.

Fifth, the RIA is particularly weak in its discussion of the distributional effects of the regulations. These distributional effects are often called impacts.

The single paragraph devoted to consumers states that "Most of the variable costs would be passed on to consumers in the form of higher prices." RIA at 54. If variable costs mean marginal costs, this statement is true; in competitive markets profit maximization results in price being set at marginal cost while fixed costs are not passed through to consumers but rather reduce profitability. Since the regulations increase marginal cost, they also increase price. But rather then provide any real analysis the RIA then simply asserts…" The average increase in the price of proposed deemed tobacco products would be very small relative to current prices." RIA at 54.

A more thorough analysis (also useful in the Regulatory Flexibility Analysis discussed following) would have estimated the average increase in price relative to current price so readers would have some idea of what FDA means by "very small." And it would have been far more useful to present this calculation by product groupings and size of the business. Unfortunately, the analysis is silent on the magnitude of the price increases in total and by product and size of business. Given the size of the markets, it is quite possible for there to be an enormous price increase for premium cigars as part of a small average price increase for all products.

The first of the two paragraphs dedicated to tobacco manufacturers, distributors, and growers says only that the regulations could lead to reduced tobacco product use and that this, in turn, may reduce their revenues. There is no estimate of current revenues or the reductions in revenues. The second paragraph only provides the number of tobacco farms and says that these farms may shift acreage to other agricultural products. The paucity of the analysis certainly violates the spirit of the EO.

A more compliant analysis would have considered the impact of the regulation on profitability, industry structure, and long-term survival. For example, the requirement for premarket tobacco applications is particularly onerous for premium cigar manufacturers. Premium cigars undergo frequent product changes and the dynamic nature of the industry requires frequent product introductions so premarket applications will be common. A leading manufacturer of premium cigars calculated that even using FDA's understated cost estimates, the cost of the premarket application for a highly successful product launch last year would have consumed more than the total of their first year's profits on this product. Using more realistic costs, they calculated that the costs would consume more than three years profits. Not surprisingly, with these costs, product launches requiring premarket applications would stop. There is also industry concern that even if it could somehow reduce the costs of the applications so they were less expensive than the FDA estimates, the FDA would not be able to process them in a timely fashion, which will also hamper the ability to introduce new products. Without new products, the industry would certainly consolidate, and in the long term, its viability would be questionable. While costs will be imposed on manufactures and retailers, the distributional effects of those costs, often referred to as impacts, will be felt not only by these industry participants, but also up and down the entire supply chain of premium cigars. Thus, there are potential impacts on tobacco growers both foreign and domestic and their work force, on importers of foreign leaf and manufactured product, on distributors, on suppliers to the industry,

on towns and cities and locations where the industry is located, on State and Federal governments, and to consumers. The RIA is close to silent on these impacts.

A more thorough analysis would have started with a better characterization of this industry as a way of setting the stage for the impacts analysis. The table below is a skeleton of an industry characterization, showing industry participants both upstream and downstream of manufacturers and rough estimates of the number of participants, production units, and dollar values of sales as applicable.

	Market Participant	How Many Participants?	$ Sales	Production Units
1.	Tobacco growers domestic (lb)	73 farms	40,896,000	4,463,159
2.	Tobacco grower overseas	75,000-100,000 workers	n/a	n/a
3.	Manufacturers domestic	18 companies	23,713,960	17,390,191
4.	Manufacturers overseas	275 -300 exporting companies	2.6 billion	2 billion
5.	Importers cigars (pc)	150-200	353,362,563	365,470,000
6.	Importers Leaf (kg)	8	42,667,433	14,525,783
7.	US Distributors	611	430,000,000	112,000,000
8.	US Retail Stores	3,000	1,048,264,338	225,433,191
9.	Tobacco curers	n/a	n/a	n/a
10.	Mail Order operations	18		
11.	Miscellaneous	Includes cigar bands, paper, cardboard, tubes, boxes		

Notes

1. MA/CT Wrapper/CT Broadleaf
2. Premium filler, binder, wrapper
3. Class H Dom. Rem.
5. Class H Imports
6. Cigar filler/wrapper/binder
8. Averages about $4.65/premium cigar including excise taxes

Sources

1. Census of Agr. - 2012
2. TMA Rough Estimate
3. TTB - December 2013, TMA Estimate
4. TMA Rough Estimate - Assuming that Altadis sales represent 10% of the world market [Altadis 2007 annual report] Cuba sold $447 mn in cigar sales in 2013. See http://online.wsj.com/article/PR-CO-20130508-916115.html
5. TTB - December 2013: Class H, TMA Estimate (but not all Class H is premium)
6. Dept. of Commerce - Dec. 2013
7. There are an estimated 1,222 tobacco product distributors in the US. About half of them sell premium cigars.
8. TTB - December 2013, TMA Estimate (Issues Monitor)

Sales at retail of premium cigars are estimated to be more than $500 million dollars. As shown in the table above, industry research shows there are more than 2,000 brick and mortar retail stores, most with over 70 percent of core sales in premium cigars, and that these employ on average 4 to 5 full time and part time employees. With the additional jobs up and down the supply chain in support of this distribution, there are certainly 10,000 domestic jobs including all

domestic elements of the supply chain there could be as many as 20,000 jobs in the industry. To the extent that these regulations reduce the use of tobacco products, revenues and profits will fall. And when cost increases cannot be passed on to consumers, revenues and profits will also fall. In response to falling revenues and profits, some firms exit the market; the remaining ones use reduced amounts of factors of production – primarily, but not exclusively, employees - in response to reduced sales. Thus, jobs in the supply chain are at risk.

While some may argue that employment losses in the tobacco industry as a result of new regulation may simply produce employment gains in other industries as consumers shift some of their spending on tobacco products to other goods and services in response to these regulations, it is indisputable that jobs will be lost in tobacco products industry. Further, any newly created jobs in other industries will not materialize instantaneously if at all: adjustments take time. And the putative new jobs will likely be in different geographic locations than those that are lost in the tobacco products industry and more diffuse with respect to industry. It is far easier to recognize the losers than to identify the winners.

The RIA is silent on the impact on localities, an impact that could be consequential. For example, Florida would be hard hit if the regulations were promulgated as proposed. There are 112 manufacturers of premium cigars based in Florida ranging from the last grand-scale cigar factory in the U.S. (the J.C. Newman Company in Tampa which employs over 130 full-time employees today) to the designated National Historic District of Ybor City, which alone has six small business handmade cigar shops – La Faraona Cigars with 3 employees, Nicahabana Cigars with 4 employees, Long Ash Cigars, with 7 employees, Ybor Cigars Plus with 4 employees, Findy Cigar Corporation with 2 employees, and Tabanero Cigars with 15 employees - as does the Little Havana community of Miami. There are also over 45 cigar corporate headquarters operations in the state and over 300 retail establishments. The industry imports leaf through the Ports of Miami, Tampa, and Fort Lauderdale and there are distribution and support services throughout the state. All will suffer the dislocations of job losses in the cigar industry and the impacts will ripple through the local economies and the state.

Pennsylvania is another hub of the industry: industry experts report that over half of all premium cigars are distributed through the state.

As another example, there would also be impacts on Las Vegas and New Orleans, which host the national cigar trade show on a rotating basis. For example, officials from Las Vegas estimate that over 17,000 people attend the various trade shows, conventions, and special events associated with premium cigars and these events provide the city with $20.7 million in non-gaming revenue. Regulations on premium cigars would certainly put these at risk. New Orleans would also suffer a direct impact on the production facility of The Cigar Factory, a manufacturer of boutique cigars in the French Quarter District, and also a tourism impact.

Further, there will also be economic impact on the two remaining communities which have cigar factories in the United States: National Cigar Company in Frankfort, Indiana ; and Avanti Cigar Company in Dunmore, Pennsylvania. It is also important to note that the threat of regulation contributed to the closure of the Finck factory in Texas and the National Cigar Company distribution facility in South Windsor, CT.

Additionally, there will be economic impact on three boutique cigar production companies located in Louisville, Lawrenceburg and Pikeville, Kentucky; and four boutique cigar production companies located in New Jersey (La Hoja Cigars, Reinado Cigars, Moya Ruiz Cigars, and Tony Santana Cigar Rolling Co.) New Jersey is also the corporate headquarters for Nat Sherman and JR's Cigars, two of the largest companies in the premium cigar sector.

There will also be an economic impact on over 44 small batch manufacturers in the newly organized American Boutique Cigar Manufacturers Association, located throughout the United States.

There will also be impacts on tobacco growers and their workers. For example, approximately 100 family farms in the Connecticut River Valley of Massachusetts and Connecticut employ over 5,000 seasonal workers, and produce a crop with an estimated value of $100 million crop. These farms are solely dependent on the premium cigar market and any impact on them has associated implications for the farm machinery, farm credit, fertilizer, fuel, farm supply and repair enterprises in the Connecticut River Valley. Given the importance of the industry to the state, it is not surprising that Congressman Joe Courtney of CT has asked the United States Secretary of Agriculture to perform an economic impact analysis of the effect of the rules on tobacco farmers in his State prior to the regulations being promulgated.

As the RIA itself notes "This proposed rule would decrease government tobacco product revenues to the extent that consumption of taxed tobacco products is reduced by this proposed rule." RIA at 54. And the RIA goes on to note that sales tax revenues for states and localities would also decline.

In addition to the domestic impacts, there are also overseas impacts. As the FDA acknowledges:

> The increase in cost, and corresponding reduction in profits, for participating in the US market would encourage foregoing manufacturers and U.S. importers to cease selling relatively low-volume products in the U.S. or consolidate products. Exit from the U.S. market could result... RIA at 55

Market exit would create heavy economic impact on the primary production nations of Honduras, Nicaragua and the Dominican Republic, where the premium cigar industry alone accounts for over 350,000 estimated jobs in the agricultural, craftsman, production, support services and distribution sectors. Implications for import/export relations, impact on foreign debt commitments due to the reliance on premium cigar production, and associated international trade implications, are not assessed in the RIA. The industry provides families with living wages, health care and education. If one considers the families reliant on the premium cigar industry for income, the number of people who would be impacted by FDA regulation of premium cigars explodes to over a million people (including thousands of jobs employing Haitian farm workers in the Dominican Republic). The negative impact and unintended consequences of this regulation could contribute to the type of economic instability the region has experienced in recent history.

Further, the user fees that the FDA would impose on premium cigar manufacturers or importers erects a barrier to the importation of the roughly 260 million premium cigars that are currently imported from our Caribbean partners. Consequently, the user fee would place a burden on commerce between the United States and the Caribbean Basin countries, thereby violating the spirit of the Dominican Republic–Central America Free Trade Agreement .

Not only would there be impacts in the Caribbean, but there would also be impact on leaf providers in Ecuador, Brazil, Costa Rica, Panama, Mexico as well as production facilities in Mexico. And impacts would also occur in Indonesia, which exports leaf and in Africa on leaf providers of Cameroon and the Central Africa Republic, which produce prized cigar wrapper leaf, with an estimated 3,000 agricultural jobs in each of these African nations.

The Regulations' Initial RFA is Deficient

An Initial Regulatory Flexibility Analysis ("IRFA") focuses on the effect of regulations on small business in the effort to solve societal problems cost-effectively:

> The premise underpinning the IRFA is that, everything else being equal, the most rational alternative is often the one that achieves the objective of the agency at the lowest cost. Since small entities often have the highest costs to comply with a rule, while contributing the least to the problem the rule addresses, it makes sense to analyze them separately from all other regulated entities to determine if the rule can be made more cost effective by employing alternative standards for small entities. The RFA in a Nutshell: A Condensed Guide to the Regulatory Flexibility Act, SBA Office of Advocacy, October 2010

The FDA recognizes that implementing these proposed regulations would "have a significant economic impact on a substantial number of small entities" and thus triggers the need for an IRFA, as required under the Regulatory Flexibility Act. RIA at 63. However, although the FDA styles the analysis as an IRFA, it is limited and incomplete and certainly does not comply with the spirit of the Act. The Office of Advocacy at the Small Business Administration also makes this point in its letter to Doctor Margaret A. Hamburg M.D., Commissioner, United States Food and Drug Administration, dated June 11, 2014.

> Based on input from small business stakeholders, Advocacy is concerned that the Initial Regulatory Flexibility Analysis (IRFA) contained in the proposed rule lacks essential information required under the Regulatory Flexibility Act (RFA)[3]. Specifically, the IRFA does not discuss the quantitative or qualitative costs of the proposed rule on many potentially affected small entities. Moreover, given the extent of the anticipated costs of this proposal, the IRFA does not adequately consider or explain significant alternatives which accomplish the stated FDA objectives while minimizing the significant economic impact of the proposal on small entities.

The starting point for any IRFA is characterizing the affected industry: a description of the affected industry and industry segments and the number of firms within each segment by

revenue grouping. Unfortunately, as FDA describes, it is not able to provide good estimates of the number of entities that would be significantly impacted in total and by size groupings. RIA at 63 to 65. Without this information, it is not possible to estimate impacts in any meaningful way.

Once industry segments are adequately characterized, the next step is to estimate the costs that the regulations will impose on firms of various sizes within each segment. The IFRA is also deficient with respect to this step; as FDA itself admits: "Because the costs of the proposed rule depend more on the number of distinct product than the number of units (or value of units sold) FDA is unable to estimate how costs would vary between larger and smaller firms." RIA at 67. Further, as discussed above, the cost analysis omits important activities and ignores the cost of increased marketing.

The lack of adequate industry characterization and cost information make impacts analysis problematic. Notwithstanding, as FDA notes for the smallest firms "we are unable to rule out the potential for them to be significantly affected by this proposed rule; some firms may exit the market." RIA at 67.

In sum, the RIA and IRFA do not show a compelling need for applying these proposed regulations to premium cigars. The economic analysis supporting the proposed regulations understates the costs of the regulations and cannot quantify any benefits. And they recognize that these proposed regulations will adversely affect small entities. As such, the RIA and the RFA are deficient.

As these comments show, on a regulatory economics, public policy, and public health basis, premium cigars pose a very small "risk." With a regulation with high costs, high impacts, and speculative benefits, society's and the FDA's scarce resources should be focused on more significant public health issues. Premium cigars should not be subjected to these proposed regulations.

Conclusion

For the reasons discussed above, the FDA should not regulate premium cigars. There is no evidence that premium cigars pose health risks, or youth access issues, comparable to other tobacco products. A "one size fits all" approach to regulation is clearly contrary to the FDA's obligation to rely on solid science to regulate tobacco products. There is ample authority in the Tobacco Control Act for differentiating between vastly different products.

Thank you for the opportunity to comment on these important issues facing the premium cigar industry.

Sincerely,

J. Glynn Loope

J. Glynn Loope
Executive Director
Cigar Rights of America

Exhibit 20

FDA NEWS RELEASE

FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death

For Immediate Release:

July 27, 2017

Español (/news-events/comunicados-de-prensa/la-fda-anuncia-un-plan-de-control-integral-para-cambiar-la-trayectoria-de-las-enfermedades-y-muertes)

The U.S. Food and Drug Administration today announced a new comprehensive plan for tobacco and nicotine regulation that will serve as a multi-year roadmap to better protect kids and significantly reduce tobacco-related disease and death. The approach places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts. The goal is to ensure that the FDA has the proper scientific and regulatory foundation to efficiently and effectively implement the Family Smoking Prevention and Tobacco Control Act. To make certain that the FDA is striking an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes, the agency is also providing targeted relief on some timelines described in the May 2016 final rule that extended the FDA's authority to additional tobacco products. The agency will also seek input on critical public health issues such as the role of flavors in tobacco products.

Tobacco use remains the leading cause of preventable disease and death in the United States, causing more than 480,000 deaths every single year. In addition to the devastating human toll caused mainly by cigarette smoking, tobacco also causes substantial financial costs to society, with direct health care and lost productivity costs totaling nearly $300 billion a year. A key piece of the FDA's approach is demonstrating a greater awareness that nicotine – while highly addictive – is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes.

"The overwhelming amount of death and disease attributable to tobacco is caused by addiction to cigarettes – the only legal consumer product that, when used as intended, will kill half of all long-term users," said FDA Commissioner Scott Gottlieb, M.D. "Unless we change course, 5.6 million young people alive today will die prematurely later in life from tobacco use. Envisioning a world where cigarettes would no longer create or sustain addiction, and where adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of our efforts – and we believe it's vital that we pursue this common ground."

The FDA plans to begin a public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable product standards. The agency intends to issue an Advance Notice of Proposed Rulemaking (ANPRM) to seek input on the potential public health benefits and any possible adverse effects of lowering nicotine in cigarettes. Because almost 90 percent of adult smokers started smoking before the age of 18 and nearly 2,500 youth smoke their first cigarette every day in the U.S., lowering nicotine levels could decrease the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit.

"Because nicotine lives at the core of both the problem and the solution to the question of addiction, addressing the addictive levels of nicotine in combustible cigarettes must be part of the FDA's strategy for addressing the devastating, addiction crisis that is threatening American families," said Commissioner Gottlieb. "Our approach to nicotine must be accompanied by a firm foundation of rules and standards for newly-regulated products. To be successful all of these steps must be done in concert and not in isolation."

The FDA is committed to encouraging innovations that have the potential to make a notable public health difference and inform policies and efforts that will best protect kids and help smokers quit cigarettes. To make this effort successful, the agency intends to extend timelines to submit tobacco product review applications for newly regulated tobacco products that were on the market as of Aug. 8, 2016. This action will afford the agency time to explore clear and meaningful measures to make tobacco products less toxic, appealing and addictive. For example, the FDA intends to develop product standards to protect against known public health risks such as electronic nicotine delivery systems (ENDS) battery issues and concerns about children's exposure to liquid nicotine. It also will provide manufacturers additional time to develop higher quality, more complete applications informed by additional guidance from the agency.

The agency plans to issue this guidance describing a new enforcement policy shortly. Under expected revised timelines, applications for newly-regulated combustible products, such as cigars, pipe tobacco and hookah tobacco, would be submitted by Aug. 8, 2021, and applications for non-combustible products such as ENDS or e-cigarettes would be submitted by Aug. 8, 2022. Additionally, the FDA expects that manufacturers would continue to market products while the agency reviews product applications.

Importantly, the anticipated new enforcement policy will not affect any current requirements for cigarettes and smokeless tobacco, only the newly-regulated tobacco products such as cigars and e-cigarettes. This approach also will not apply to provisions of the final rule for which compliance deadlines already have passed, such as mandatory age and photo-ID checks to prevent illegal sales to minors. It also will not affect future deadlines for other provisions of the rule, including, but not limited to, required warning statements, ingredient listing, health document submissions, harmful and potentially harmful constituent reports, and the removal of modified risk claims, i.e., "light," "low," or "mild," or similar descriptors.

In order to further explore how best to protect public health in the evolving tobacco marketplace, the agency also will seek input from the public on a variety of significant topics, including approaches to regulating kid-appealing flavors in e-cigarettes and cigars. In particular, the FDA intends to issue ANPRMs to: 1) seek public comment on the role that flavors (including menthol) in tobacco products play in attracting youth and may play in helping some smokers switch to potentially less harmful forms of nicotine delivery; and 2) solicit additional comments and scientific data related to the patterns of use and resulting public health impacts from premium cigars, which were included in the FDA's 2016 rule. Additionally, the agency plans to examine actions to increase access and use of FDA-approved medicinal nicotine products, and work with sponsors to consider what steps can be taken under the safety and efficacy standard for products intended to help smokers quit.

"This comprehensive plan and sweeping approach to tobacco and nicotine allows the FDA to apply the powerful tools given by Congress to achieve the most significant public health impact," said Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products. "Public input on these complex issues will help ensure the agency has the proper science-based policies in place to meaningfully reduce the harms caused by tobacco use."

To complement these larger policy considerations, the FDA plans to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers, while upholding the agency's public health mission. Among other things, the FDA intends to issue regulations outlining what information the agency expects to be included in Premarket Tobacco Applications (PMTAs), Modified Risk Tobacco Product (MRTP) applications and reports to demonstrate Substantial Equivalence (SE). The FDA also plans to finalize guidance on how it intends to review PMTAs for ENDS. The agency also will continue efforts to assist industry in complying with federal tobacco regulations through online information, meetings, webinars and guidance documents.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the

safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media:

Michael Felberbaum (mailto:michael.felberbaum@fda.hhs.gov)

240-402-9548

Consumer:

888-INFO-FDA

Related Information

- Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco)
- FDA's New Plan for Tobacco and Nicotine Regulation (/tobacco-products/newsroom/fdas-comprehensive-plan-tobacco-and-nicotine-regulation)
- FDA Center for Tobacco Products (/tobacco-products)

Agency to pursue lowering nicotine in cigarettes to non-addictive levels and create more predictability in tobacco regulation

More Press Announcements (/news-events/newsroom/press-announcements)

Exhibit 21

View Rule

View EO 12866 Meetings | Printer-Friendly Version | Download RIN Data in XML

HHS/FDA **RIN:** 0910-AH89 **Publication ID:** Spring 2019

Title: Format and Content of Reports Intended to Demonstrate Substantial Equivalence

Abstract:

This proposed rule would establish the format and content of reports intended to demonstrate substantial equivalence (SE) in tobacco products and would provide information as to how the Agency will review and act on these submissions.

Agency: Department of Health and Human Services(HHS)
Priority: Other Significant
RIN Status: Previously published in the Unified Agenda
Agenda Stage of Rulemaking: Proposed Rule Stage
Major: No
Unfunded Mandates: No
EO 13771 Designation: Deregulatory
CFR Citation: 21 CFR 1107
Legal Authority: 21 U.S.C. 371 21 U.S.C. 374 21 U.S.C. 387 42 U.S.C. 4332
Legal Deadline: None
Timetable:

Action	Date	FR Cite
NPRM	04/02/2019	84 FR 12740
NPRM Comment Period End	06/17/2019	
Final Action	04/00/2020	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: None
Federalism: No
Included in the Regulatory Plan: Yes
RIN Data Printed in the FR: No
Agency Contact:

Annette L. Marthaler
Supervisory Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335,
Silver Spring, MD 20993
Phone:877 287-1373
Fax:877 287-1426
Email: ctpregulations@fda.hhs.gov

Exhibit 22

Nicotine & Tobacco Research, 2018, 1457–1466
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Original investigation
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Original investigation

US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014

Catherine G. Corey MSPH[1], Enver Holder-Hayes MPH[1], Anh B. Nguyen PhD[1], Cristine D. Delnevo PhD[2], Brian L. Rostron PhD[1], Maansi Bansal-Travers PhD[3], Heather L. Kimmel PhD[4], Amber Koblitz PhD[1], Elizabeth Lambert MSc[4], Jennifer L. Pearson PhD[5], Eva Sharma PhD[6], Cindy Tworek PhD[1], Andrew J. Hyland PhD[3], Kevin P. Conway PhD[4], Bridget K. Ambrose PhD[1], Nicolette Borek PhD[1]

[1]Center for Tobacco Products, US Food and Drug Administration, Silver Spring, MD; [2]Center for Tobacco Studies, School of Public Health, Rutgers University, Piscataway, NJ; [3]Department of Health Behavior, Roswell Park Cancer Institute, Buffalo, NY; [4]National Institute on Drug Abuse, National Institutes of Health, Bethesda, MD; [5]Schroeder Institute for Tobacco Research and Policy Studies, Truth Initiative, Washington, DC; [6]Westat, Rockville, MD

Corresponding Author: Catherine G. Corey, MSPH, Office of Science, Center for Tobacco Products, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, USA. Telephone: 301-796-7396; Fax: 301-595-1138; E-mail: catherine.corey@fda.hhs.gov

Abstract

Introduction: The US cigar market is diverse, yet until recently most research studies and tobacco surveillance systems have not reported behavioral and related outcomes by cigar type.
Methods: The 2013–2014 Population Assessment of Tobacco and Health Study collected data separately for filtered cigars (FCs), cigarillos, and traditional cigars, which were further distinguished as premium or nonpremium. Descriptive statistics for adult established current smokers of each cigar type and cigarettes were calculated for demographic characteristics, tobacco use patterns, purchasing behaviors and reasons for use. Adjusted prevalence ratios (APRs) using a marginal predictions approach with logistic regression assessed correlates of dual cigar and cigarette smoking.
Results: Age, sex, race/ethnicity, education level, and poverty status of smokers varied according to cigar type. Daily cigar smoking prevalence and number of cigars smoked per day were higher for FCs (37.3%; median: 1.6 cigars/day, respectively), than all other cigar types (6.7%–25.3%, all $p < .01$; 0.1–0.4 cigars/day, all $p < .01$, respectively); daily smoking and cigars per day were similar for nonpremium cigars and cigarillos ($p = .11$; $p = .33$, respectively). Cigarette smoking was twice as common among smokers of nonpremium cigars, cigarillos, and FCs (58.0%–66.0%) than among premium cigars (29.9%). Among current cigar smokers, FC smokers (APR = 1.23, 95% confidence interval [CI] = 1.09–1.39), other tobacco product users (APR = 1.27, 95% CI = 1.15–1.41), and those

with a GED/high school diploma or less (APR = 1.20, 95% CI = 1.09–1.33) were more likely to also smoke cigarettes.

Conclusion: User characteristics, cigar smoking patterns, and dual smoking with cigarettes varied by cigar type highlighting the importance of adequately describing the cigar type studied and, where appropriate, differentiating results by cigar type.

Implications: Despite the diversity of the cigar market place, historically many research studies and tobacco surveillance systems have treated cigars as a single product type. This study describes similarities and differences in the user characteristics, tobacco use patterns, and purchasing behaviors of premium, nonpremium, cigarillo, and filtered cigar smokers. To enhance tobacco regulatory science, sufficient descriptions of the cigar type(s) studied and, where appropriate, differentiation of the particular cigar type(s) studied should be undertaken to improve the interpretation of study findings, understanding of cigar use patterns and related behaviors and future approaches to reducing cigar-attributable morbidity and mortality.

Introduction

Annual cigar consumption in the United States doubled from 6.2 billion cigars in 2000 to 12.0 billion cigars in 2016.[1] Cigar smoke contains many of the same toxic and carcinogenic constituents present in cigarette smoke.[2] Regular cigar smoking is estimated to cause approximately 9000 premature deaths annually in the United States primarily from cancers of the lung and upper aerodigestive tract, cardiovascular disease, and chronic obstructive pulmonary disease.[3] Despite the growth in cigar consumption and serious health risks associated with cigar smoking,[2–7] data systems that monitor tobacco use generally provide less detailed information on cigar smoking behaviors and product attributes as a whole and by subtypes compared with data collected for cigarettes.[8–11] Furthermore, data on purchasing behaviors, including where, how, and at what price cigars are bought, as well as beliefs about smoking particular cigar types, have not previously been systematically collected.

Federal regulations define a cigar as "any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco."[12] For federal tax purposes, the US Treasury Department differentiates cigars by weight as either small (≤3 pounds per 1000 cigars) or large (>3 pounds per 1000 cigars).[13] Yet, cigars come in a range of shapes and sizes, and vary in their manufacturing processes, packaging sizes, and prices; to date, no federal regulatory definitions further classify cigars to account for the diverse array of products[14] and the myriad of ways they are marketed to the public and referred to by consumers.[15–20] In a previous national telephone-based survey, cigars were distinguished into three types: premium large cigars, cigarillos, and other mass-market (ie, nonpremium) cigars, and filtered cigars (FCs), based on the size/length, components (eg, filters, tips), and cigar brand that was usually smoked.[21] In general, premium cigars, also referred to as "stogies," consist of more expensive tobacco varieties and components, such as whole tobacco leaf wrapper and binder, and may be assembled by hand. Cigarillos and other larger mass market cigars are generally machine-produced using homogenized tobacco leaf or reconstituted tobacco, and may be sold with plastic or wooden tips. FCs are generally similar to cigarettes in shape, size, and other features and are generally sold in packs or by the carton, like cigarettes.[22–24]

Preference for particular cigar types can vary according to individual user characteristics (eg, sex, age, socioeconomic status), frequency (eg, daily vs. some days) and the extent of co-use with other substances, including cigarettes and marijuana.[9,11,15,21,25,26] Co-use or dual use of cigars and cigarettes has been a focus of recent studies as cigarette smoking prevalence has declined and the diversity of non-cigarette tobacco products has grown.[9-11,21,27–31] Among the tobacco products that have received particular attention are "little cigars and cigarillos" (or "LCCs") and their relationship to cigarette smoking. Studies suggest that the relationship between LCCs and cigarette smoking is influenced by factors such as (1) differences in local, state and federal tobacco tax rates, (2) regulations on cigarette flavoring, minimum pack sizes, and advertising restrictions, (3) marketing strategies, including price promotions by tobacco manufacturers, and (4) perceptions among young people about the risks or harms of smoking cigars generally or relative to cigarette smoking.[11,27,28,32–34] Related work has explored how LCC risk perceptions vary according to tobacco flavorings and co-use of other substances.[31,35] However, to date, information specific to each cigar type has been limited, as has data on a full range of tobacco-related behaviors.

The current study describes individual user characteristics, tobacco use patterns, purchasing behaviors, and reasons for use separately for traditional premium and nonpremium cigars, cigarillos, FCs, and cigarettes. This analysis adds to the small body of empirical evidence on the similarities and differences across cigar types and cigarettes. These comprehensive data can provide a better understanding of the cigar marketplace and inform future strategies to reduce the death and disease from cigar smoking.

Methods

Sample

The PATH Study is a nationally representative, longitudinal cohort study of 45 971 adults and youth in the United States, aged 12 years and older. The National Institutes of Health, through the National Institute on Drug Abuse, is partnering with the Food and Drug Administration's Center for Tobacco Products to conduct the PATH Study under a contract with Westat. The PATH Study uses Audio Computer-Assisted Self-Interviews to collect self-report information on tobacco-use patterns and related health behaviors. The PATH Study recruitment employed a stratified address-based, area-probability sampling that oversampled adult tobacco users, adults aged 18–24 years, and African American adults. An in-person screener was used to select youths and adults from households for participation. This analysis draws from the adult interviews (n = 32 320 participants aged 18 years and older) since adults were asked more detailed tobacco purchasing questions compared with youth. Among households screened for wave 1 (weighted household screener rate = 54.0%), the overall

adult interview weighted response rate was 74.0%. The weighting procedures adjusted for oversampling and nonresponse; combined with the use of a probability sample, the weighted data allow the estimates produced by the PATH Study to be representative of the noninstitutionalized, civilian US population. Further details regarding the PATH Study design, methods, and study instrument (including cigar images) are published elsewhere.[36,37] The PATH Study was approved by the Institutional Review Board at Westat, and the Office of Management and Budget approved the data collection. This analysis relies on data collected from wave 1, fielded from September 2013 to December 2014 and analyzed in 2015–2016.

Measures

To distinguish cigar types, the PATH Study questionnaire first displays images of traditional cigars with accompanying text describing the physical characteristics and listing examples of popular brands ("*Traditional cigars contain tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta, and Arturo Fuente, but there are many others.*") Then the questionnaire displays images of cigarillos and FCs with text: "*Cigarillos and filtered cigars are smaller than traditional cigars. They are usually brown. Some are the same size as cigarettes, and some come with tips or filters. Some common brands are Black & Mild, Swisher Sweets, Dutch Masters, Phillies Blunts, Prime Time, and Winchester.*" That is followed by a question about the kind of FCs or cigarillos smoked. Participants who reported smoking cigars "*with a filter (like a cigarette filter)*" were assigned as FC smokers, whereas those reporting having smoked cigars "*with a plastic or wooden tip*" or "*without a tip or filter*" were assigned as cigarillo smokers. Nearly half of all cigarillo smokers (45%) used both tipped and untipped cigarillos. Sensitivity analyses (not shown) indicated that three groups of cigarillo users: dual tipped and untipped, tipped only, and untipped only shared similar use behaviors and profiles, consequently cigarillos were analyzed as a single category.

Current Established Cigar Smokers

Participants who had ever heard of the cigar type, ever smoked the cigar type "*fairly regularly*," and now smoked the cigar type every day or some days were defined as current established cigar smokers. Those smoking more than one of the three cigar types (ie, traditional cigar, cigarillo, FC) were administered the cigar module for each cigar type smoked. For this analysis, traditional cigars were further differentiated as premium or nonpremium based on the tobacco blends, components, manufacturing process and other characteristics associated with the usual brand smoked (Supplementary Table A). Relying on usual brand smoked, approximately 10% of traditional cigar smokers could not be assigned a premium status. Among those who *were* assigned as premium smokers, 90% paid, on average, ≥$2 per cigar, and a similar percentage assigned as nonpremium smokers paid <$2 per cigar. Therefore, those with nonusable brand information who paid ≥$2 per cigar were designated as premium cigar smokers, whereas those paying <$2 were assigned as nonpremium. This analysis comprises four cigar types: traditional premium, traditional nonpremium, cigarillos, and FCs.

Current Established Cigarette Smokers

Participants who had smoked at least 100 manufactured or roll-your-own cigarettes in their lifetime and now smoked cigarettes every day or some days were defined as current established cigarette smokers.

Cigar Smoking Patterns

For this analysis, the lifetime number of cigars smoked was categorized as: 10 or fewer cigars, 11–50 cigars, and 51 or more cigars, the upper category intended to be consistent with the lifetime threshold for cigar use applied on national adult tobacco surveys.[38–39] Daily smoking was ascertained from the frequency (ie, every day, some days) the cigar type was smoked. Number of days smoked in the past 30 days was collected continuously for some day smokers; every day smokers were assigned as smoking on all 30 days. Number of cigars smoked per day for each cigar type was calculated for daily and some day smokers; among those who smoked on 0–29 of the past 30 days, this value was calculated as the number of days smoked multiplied by the number of cigars smoked on those days divided by 30 (days). Duration of smoking was calculated by subtracting age at first regular use from current age. Current use of ≥1 other noncigar, noncigarette product(s) was defined as having ever used at least one of the following tobacco products "fairly regularly" and now using that product every day or some days: e-cigarettes, pipe tobacco, hookah, snus pouches, other smokeless tobacco (ie, loose snus, moist snuff, dip, spit, chewing tobacco), or dissolvable tobacco.

Cigar Purchasing

Participants reported whether they had a regular brand, the name of the regular brand, and whether the brand was flavored. They also indicated how (in person, from the internet, by telephone or did not buy their own tobacco product) and where (convenience store/gas station, smoke shop/tobacco specialty or outlet store, or somewhere else) they purchased cigars. Participants reported their usual cigar purchase size as single stick or box/pack. Price per cigar was calculated as the usual price the participant reported paying divided by the number of cigars sold in the usual unit purchased. For cigarette smokers, corresponding smoking and purchasing measures were created and reported when applicable.

Reasons for Cigar Smoking

Participants were asked a total of 12 reasons or beliefs (in a randomized order) why people may smoke cigars and indicated whether each applied to them ("yes"/"no"). Reasons included: "*They are affordable*"; "*I like socializing while smoking them*"; and "*They come in flavors I like*." The full set is reported in Supplementary Table B. Reasons that included comparisons to cigarettes were stratified according to the participant's cigarette smoking status.

Demographic Characteristics

Participants reported the following demographic characteristics: sex (male, female); age in years, categorized as: 18–24, 25–34, 35–54, ≥55; race and ethnicity, categorized as: white non-Hispanic (NH) ("white"), black/African American NH ("black"), other/multi-race NH, Hispanic; education status, categorized as: less than high school diploma, GED, high school diploma, some college/associate's degree, completed college or more. Based on annual household income and household size, poverty status was assigned following federal guidelines as: <100% federal poverty level (FPL), 100–<200% FPL, and ≥200% FPL.

Data Analysis

Prevalence estimates for smoking each of the four cigar types and cigarettes were produced in SAS version 9.3 (SAS Institute, Cary, NC) according to demographics, tobacco use patterns, purchasing behaviors, and reasons for use. Tests for differences among smokers of each of the four cigar types or cigarettes were conducted in SAS using

simple linear regression for categorical variables, and were conducted in Stata version 14.2 (StataCorp, College Station, TX) using quantile regression for continuous variables not normally distributed. Adjusted prevalence ratios (APRs) were obtained using a marginal predictions approach with logistic regression[40] in SAS-callable SUDAAN version 11.0.1 (RTI International, RTP, NC) to examine associations between dual cigar and cigarette smoking versus cigar-only smoking according to demographics and cigar use behaviors. All analyses were conducted using replicate weights and balanced repeated replication methods (BRR) to account for the PATH Study's complex survey design.[36–37] For the tests of differences described above, the BRR method implicitly accounts for any correlation between the estimates of groups being compared.[41] Prevalence estimates with a relative standard error of >30% or denominator with <50 observations were suppressed. Variables missing values for >5% of all eligible responses (eg, FPL) were treated as a separate analytic category; otherwise, observations with missing values were dropped from analysis.

Results

Demographic Characteristics of Cigar and Cigarette Smokers

The overall prevalence of current established adult tobacco use was 0.7% for premium cigars, 0.8% for nonpremium cigars, 1.7% for cigarillos, 0.9% for FCs, and 18.1% for cigarettes (Table 1). Males comprised the majority of adult cigar (68.6%–95.8%) and cigarette (55.3%) smokers. Younger adults (aged 18–34 years) accounted for 64.5% of cigarillo smokers and 34.0%–46.8% of smokers of the other products (ie, premium cigars, nonpremium cigars, FCs). Black adults comprised 35.7% of cigarillo and 24.2% of nonpremium cigar smokers and 5.3%–15.7% of smokers of other products. Adults with a GED/high school diploma or less accounted for most smokers of cigarettes (54.8%) and all cigars (54.0%–59.2%) except premium cigars (26.2%). Adults living below the federal poverty level comprised 34.2% of cigarette and 41.2%–47.1% of all cigar smokers, except premium cigars (14.2%).

Cigar and Cigarette Smoking Patterns

Although most established cigar smokers (62.0%–71.6%) had smoked more than 50 of that cigar type in their lifetime, cigar smoking patterns and tobacco use behaviors varied by cigar type (Table 2). Prevalence of daily smoking was higher for FCs (37.3%), compared with all other cigar types (6.7%–25.3%; all $p < .01$); daily smoking was similar for nonpremium cigars and cigarillos ($p = 0.11$). Cigars smoked per day were greater for FCs (median: 1.6 cigars/day) compared with all other cigar types (0.1–0.4 cigars/day; all $p < .01$); cigars per day were similar for nonpremium cigars and cigarillos ($p = .33$). Age at first regular use was higher for FCs (median:

Table 1. Demographic Characteristics of Adult Current Established Traditional Cigar (Premium, Nonpremium), Cigarillo, Filtered Cigar, and Cigarette Smokers, PATH Study Wave 1, 2013–2014

	Premium cigars[a] (*n* = 377)	Nonpremium cigars[a] (*n* = 489)	Cigarillos (*n* = 1186)	Filtered cigars (FCs) (*n* = 551)	Cigarettes (*n* = 11 402)
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Overall adult prevalence	0.7 (0.6–0.7)	0.8 (0.7–0.8)	1.7 (1.5–1.8)	0.9 (0.8–1.0)	18.1 (17.6–18.6)
Sex					
Male	95.8 (93.5–98.0)	83.9 (80.2–87.6)	72.7 (70.1–75.4)	68.6 (64.6–72.7)	55.3 (54.2–56.4)
Female	4.2 (2.0–6.5)	16.1 (12.4–19.8)	27.3 (24.6–29.9)	31.4 (27.3–35.4)	44.7 (43.6–45.8)
Age group (years)[b]					
18–24	17.5 (12.3–22.6)	22.1 (18.3–25.9)	35.9 (32.5–39.3)	18.0 (14.2–21.7)	14.1 (13.3–14.8)
25–34	25.5 (20.0–31.0)	24.7 (20.3–29.2)	28.6 (25.2–31.9)	16.0 (12.4–19.6)	24.3 (23.4–25.1)
35–54	34.4 (29.3–39.6)	32.9 (27.7–38.2)	27.1 (23.9–30.2)	39.8 (35.3–44.3)	39.0 (38.0–40.1)
55+	22.6 (17.6–27.6)	20.2 (15.8–24.6)	8.5 (6.6–10.4)	26.3 (22.0–30.5)	22.7 (21.8–23.5)
Race/ethnicity					
White, non-Hispanic	77.2 (71.9–82.4)	58.2 (53.3–63.2)	41.7 (38.3–45.0)	66.2 (61.5–70.9)	69.8 (68.6–71.0)
Black/AA, non-Hispanic	5.3 (2.3–8.3)	24.2 (19.5–28.9)	35.7 (32.1–39.2)	15.7 (11.0–20.4)	12.9 (12.2–13.7)
Other or multi-race, non-Hispanic	6.6 (3.6–9.6)	5.9 (3.5–8.2)	6.6 (5.3–7.9)	6.6 (4.3–8.9)	6.0 (5.5–6.5)
Hispanic	10.9 (7.3–14.6)	11.7 (8.6–14.8)	16.0 (14.0–18.0)	11.5 (8.7–14.3)	11.2 (10.6–11.9)
Education					
Less than high school diploma	5.4 (3.1–7.8)	14.2 (10.7–17.8)	16.0 (13.9–18.1)	17.7 (14.5–21.0)	15.9 (15.2–16.7)
GED	4.6 (2.3–6.8)	12.2 (9.3–15.1)	11.7 (10.0–13.5)	11.7 (8.8–14.6)	10.8 (10.1–11.6)
High school diploma	16.2 (12.0–20.4)	28.4 (24.2–32.5)	26.3 (23.2–29.3)	29.8 (25.3–34.3)	28.1 (26.9–29.4)
Some college/associate degree	34.9 (29.6–40.3)	38.5 (34.0–43.0)	38.2 (35.0–41.4)	33.0 (29.2–36.9)	33.8 (32.7–35.0)
Completed college or more	38.9 (33.2–44.5)	6.7 (4.3–9.2)	7.8 (6.1–9.6)	7.8 (5.1–10.4)	11.2 (10.6–11.9)
Household poverty					
<100% FPL	14.2 (10.7–17.7)	41.2 (36.4–46.0)	47.1 (43.6–50.5)	44.9 (40.1–49.8)	34.2 (32.9–35.4)
100–<200% FPL	15.4 (11.4–19.3)	22.2 (18.6–25.9)	23.6 (20.9–26.3)	27.4 (23.1–31.8)	25.1 (24.2–26.0)
≥200% FPL	62.7 (57.3–68.0)	29.0 (24.3–33.6)	22.6 (19.1–26.0)	18.4 (15.2–21.7)	32.3 (30.9–33.6)
Missing FPL	7.8 (4.7–10.8)	7.6 (5.1–10.1)	6.8 (4.9–8.7)	9.2 (6.2–12.2)	8.5 (7.8–9.2)

CI, Wald confidence interval; AA, African-American; GED, General Education Development certificate; FPL, federal poverty level.

[a]Among traditional established cigar smokers 3% (*n* = 24) could not be assigned as either a premium or nonpremium smoker after assessing responses to usual brand (Supplementary Table A).

[b]When respondent age was missing, imputed values for age were used as described in the PATH Restricted Use File User Guide (United States Department of Health and Human Services, 2017).

Table 2. Smoking Patterns Among Adult Current Established Traditional Cigar (Premium, Nonpremium), Cigarillo, Filtered Cigar, and Cigarette Smokers, PATH Study Wave 1, 2013–2014

	Premium cigars	Nonpremium cigars	Cigarillos	Filtered cigars (FCs)	Cigarettes[a]
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Lifetime cigars smoked					
<1–10 cigars	4.9 (2.8–7.1)	16.8 (13.5–20.1)	7.8 (6.2–9.4)	8.1 (5.3–10.8)	NA
11–50 cigars	23.4 (18.3–28.6)	21.2 (17.4–25.1)	20.9 (18.4–23.4)	21.1 (17.0–25.1)	NA
51 or more cigars	71.6 (66.5–76.8)	62.0 (57.9–66.0)	71.3 (68.6–74.1)	70.9 (67.0–74.8)	NA
Now smoke product every day	6.7 (4.1–9.3)	25.3 (21.3–29.3)	22.0 (19.7–24.2)	37.3 (31.9–42.7)	79.5 (78.5–80.6)
Days smoked in past 30 days[b] (median, IQR)	1.7 (0.0–4.8)	9.2 (1.5–28.5)	7.5 (1.3–29.1)	14.0 (0.8–28.8)	29.4 (29.1–29.7)
Number of cigars or cigarettes/day[c] (median, IQR)	0.1 (0.0–0.2)	0.4 (0.1–2.0)	0.3 (0.1–2.0)	1.6 (0.1–9.5)	10.1 (5.0–19.6)
Age (years) at first regular use[d] (median, IQR)	24.5 (18.8–32.6)	19.5 (16.6–29.6)	18.0 (15.9–23.3)	26.8 (17.8–44.3)	16.6 (14.7–18.7)
Duration (years) since first regular[d] use (median, IQR)	8.7 (3.4–16.8)	10.9 (4.3–18.0)	7.3 (3.3–13.9)	5.4 (1.7–14.4)	21.8 (10.8–35.3)
Currently use ≥1 other cigar type(s)[e,f]	16.8 (12.4–21.3)	64.0 (58.7–69.3)	37.7 (34.1–41.2)	41.6 (36.3–46.8)	9.0 (8.4–9.7)
Currently use ≥1 noncigar, noncigarette product(s)[g]	33.7 (29.5–38.0)	31.4 (26.7–36.1)	28.8 (26.0–31.6)	27.1 (23.1–31.1)	15.8 (15.0–16.6)
Cigarette smoking status[h]					
Current established smoker	29.9 (25.5–34.3)	59.5 (54.6–64.4)	58.0 (54.4–61.6)	66.0 (61.3–70.7)	NA
Former established smoker	28.3 (23.0–33.6)	15.6 (11.9–19.3)	10.6 (8.4–12.8)	10.6 (7.5–13.8)	NA
Never smoker	41.8 (36.9–46.7)	24.9 (21.0–28.9)	31.4 (28.2–34.6)	23.4 (18.9–27.8)	NA

CI, Wald confidence interval; IQR, interquartile range (25th and 75th percentiles); NA, not applicable.

[a]When respondent reported smoking both manufactured cigarettes and roll-your-own (RYO) cigarettes (n = 554), for certain topics they were asked separate questions about each product. For dual manufactured cigarette and RYO smokers, the responses to manufactured cigarette products are provided; otherwise, responses reflect the single cigarette type the respondent reported smoking.

[b]Number of days using the product in past 30 days was asked of those who now smoke cigars some days; every day smokers assumed to smoke on all 30 days.

[c]Respondents reporting smoking less than one cigar per day on the days smoked were assigned as smoking 0.5 cigars per day.

[d]Those reporting age at first regular use <6 years were assigned a value of 6 years.

[e]For current cigarette smokers, "currently use ≥1 other cigar products" refers to current smoking of one or more cigar products.

[f]If respondent was missing status for one cigar product and did not smoke the other cigar product, then treated as not smoking other cigar types.

[g]Current use of ≥1 noncigar, noncigarette product(s) defined as having ever used one or more of the following tobacco products "fairly regularly" and now using that product every or some days: e-cigarettes, pipe tobacco, hookah, smokeless tobacco, snus, or dissolvable tobacco. If respondent reported not using any other tobacco product, or some combination of not using and missing tobacco product use status, then treated as not using any noncigar, noncigarette products.

[h]Former established cigarette smokers had to have smoked at least 100 cigarettes in their lifetime and now smoke cigarettes not at all; never cigarette smokers had to smoke less than 100 cigarettes in their lifetime.

26.8 years) and premium cigars (24.5 years) compared with nonpremium cigars, cigarillos and cigarettes (16.6–19.5 years; all $p < .05$). Currently smoking one or more of the other cigar products ranged from 64.0% for nonpremium cigars to 16.8% for premium cigars. Current cigarette smoking was twice as common for those smoking nonpremium cigars, cigarillos, and FCs (58.0%–66.0%) than premium cigars (29.9%), and cigarette smoking status among those smoking FCs differed from that of cigarillos and premium cigars ($p < .01$). The use of noncigar/noncigarette tobacco products was lower among those smoking FCs (27.1%) than among those smoking premium cigars (33.7%; $p = .03$), and was similar to those smoking nonpremium cigars (31.4%; $p = .16$) and cigarillos (28.8%; $p = .46$).

Tobacco Product Characteristics and Purchasing Behaviors

Having a regular tobacco brand was reported by at least three-quarters (77.1%–93.1%) of smokers of nonpremium cigars, cigarillos, FCs, and cigarettes versus half (49.7%) of smokers of premium cigars (Table 3). Swisher Sweets was among the leading brands of nonpremium cigars, cigarillos, and FCs (21.7%–23.6%). Dutch Masters, Black & Mild, and White Owl brands were together reported by 59.3% of cigarillo and 32.8% of nonpremium cigar smokers, while Cheyenne, Phillies, and Prime Time were together reported by nearly 30% of FC smokers. Reporting use of a flavored usual brand occurred less frequently for premium cigars (11.9%) compared with all other cigar types (53.0%–61.0%, all $p < .01$). Nearly all nonpremium cigars, cigarillos, FCs, and cigarettes were purchased in person (95.5%–97.2%) and most were bought in convenience stores/gas stations (75.4%–86.8%). In contrast, for premium cigars, nearly one-quarter of smokers did not buy in person; smoke shops/specialty stores (46.8%) and cigar bars (29.9%) were the primary purchase locations. The median price paid per stick was lower for FCs ($0.12) than cigarettes ($0.27), nonpremium cigars or cigarillos ($1.00), or premium cigars ($7.49) (all $p < .01$).

Factors Associated With Dual Cigar and Cigarette Smoking Versus Cigar-Only Smoking

Among current cigar smokers, those smoking FCs were more likely to be dual cigarette smokers (APR = 1.23, 95% CI = 1.09–1.39), while those smoking premium cigars were less likely to also smoke

Table 3. Tobacco Product Characteristics and Purchasing Behaviors Among Adult Current Established Traditional Cigar (Premium, Nonpremium), Cigarillo, Filtered Cigar and Cigarette Smokers, PATH Study Wave 1, 2013–2014

	Premium cigars	Nonpremium cigars	Cigarillos	Filtered cigars (FCs)	Cigarettes[a]
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Has a regular brand	49.7 (44.4–54.9)	77.1 (73.8–80.5)	83.0 (80.8–85.3)	82.9 (79.4–86.4)	93.1 (92.5–93.6)
Top 5 brands smoked[b]	Cohiba 16.9 (12.8–20.9)	Swisher Sweets 21.7 (17.0–26.3)	Black & Mild 42.8 (39.4–46.2)	Swisher Sweets 22.5 (17.7–27.4)	Marlboro 38.3 (36.8–39.8)
	Macanudo 15.2 (11.4–19.0)	Dutch Masters 16.7 (13.0–20.5)	Swisher Sweets 23.6 (20.9–26.3)	Cheyenne 13.4 (10.3–16.5)	Newport 14.6 (13.4–15.8)
	Arturo Fuente 13.5 (9.6–17.5)	Backwoods 11.3 (8.1–14.5)	White Owl 10.5 (8.5–12.5)	Phillies 7.9 (5.3–10.4)	Camel 10.1 (9.3–10.9)
	Acid 6.9 (3.6–10.1)	Black & Mild 9.7 (6.7–12.6)	Dutch Masters 6.0 (4.3–7.6)	Prime Time 7.2 (4.1–10.4)	Pall Mall 6.5 (5.8–7.1)
	Montecristo 6.5 (3.1–9.9)	White Owl 6.4 (4.0–8.8)	Zig Zag 2.2 (1.3–3.1)	Djarum 6.8 (4.1–9.4)	Kool 2.6 (2.0–3.3)
Regular brand flavored or mentholated[b,c,d]	11.9 (8.0–15.8)	53.0 (47.7–58.3)	61.0 (57.5–64.5)	60.4 (56.3–64.4)	37.1 (35.8–38.4)
Usually buy in person	77.6 (72.8–82.4)	96.7 (94.8–98.6)	96.7 (95.7–97.8)	95.5 (93.4–97.7)	97.2 (96.9–97.6)
Where buy tobacco product[e]					
Cigar bar	29.9 (24.1–35.6)	*	^	*	NA
Convenience store/gas station	18.2 (13.6–22.8)	78.5 (74.1–83.0)	85.1 (82.5–87.7)	75.4 (70.6–80.2)	86.9 (85.2–88.5)
Smoke shop/tobacco specialty or outlet store	46.8 (40.5–53.2)	18.4 (14.5–22.4)	12.2 (9.8–14.7)	22.0 (17.5–26.5)	10.9 (9.3–12.5)
Somewhere else	5.1 (2.2–8.0)	*	*	*	2.2 (1.5–2.9)
Usual purchase size[f]					
Single	79.1 (73.6–84.6)	44.5 (39.5–49.5)	49.4 (46.1–52.7)	13.8 (10.6–17.0)	1.8 (1.5–2.1)
Box or pack	20.9 (15.4–26.4)	55.5 (50.5–60.5)	50.6 (47.3–53.9)	86.2 (83.0–89.4)	82.0 (80.6–83.3)
Carton	NA	NA	NA	NA	16.2 (14.8–17.6)
Price per stick[f,g] (median, IQR)	$7.49 (4.53–9.93)	$1.00 (0.60–1.40)	$1.00 (0.60–1.10)	$0.12 (0.08–0.26)	$0.27 (0.23–0.32)

CI, Wald confidence interval; IQR, interquartile range (25th and 75th percentiles); NA, not applicable.

[a]When respondent reported smoking both manufactured cigarettes and roll-your-own (RYO) cigarettes (n = 554), for certain topics they were asked separate questions about each product. For dual manufactured cigarette and RYO smokers, the responses to manufactured cigarette products are provided; otherwise, responses reflect the single cigarette type the respondent reported smoking.

[b]Among those with a regular brand or if no regular brand, then refers to last brand purchased.

[c]Cigar and RYO smokers were asked whether their regular brand was flavored to taste like menthol, mint, clove, spice, candy, fruit, chocolate, alcohol or other sweets.

[d]Manufactured cigarette and RYO smokers were asked whether their regular brand was mentholated.

[e]Only asked of those who usually buy in person. Where buy tobacco product refers where purchasing most of the time. "Convenience store/gas station" category also includes supermarket, grocery store, warehouse, liquor store; "somewhere else" category also includes duty free shop, military commissary, bar/pub, restaurant, casino, friend, relative, swap meet/flea market, store on an Indian reservation.

[f]For cigar smokers, restricted to usually buy in person; for cigarettes, asked of manufactured cigarette smokers, irrespective of buying in person or not.

[g]Among FC smokers, price per stick is restricted to those who reported purchasing either 20 or 12 count packs (63% of all FC smokers).

*Estimate has been suppressed because it is statistically unreliable. It is based on a (denominator) sample size of less than 50, or the relative standard error of the estimate (or its complement) is larger than 30 percent.

^The estimate's 95% CI is (0.7–2.3); the estimate is reliable however it is not reported to avoid deducing the value of the suppressed estimate in this column.

cigarettes (APR = 0.52, 95% CI = 0.40–0.67) (Table 4). Cigar smokers who currently used additional tobacco products (eg, e-cigarettes, hookah, smokeless tobacco) were more likely to also smoke cigarettes (APR = 1.27, 95% CI = 1.15–1.41). Compared to whites, black cigar smokers (APR = 0.82, 95% CI = 0.72–0.94) were less likely to also smoke cigarettes. Cigar smokers with a GED/high school diploma or less were more likely (APR = 1.20, 95% CI = 1.09–1.33) than those with at least some college to also smoke cigarettes. Those who reported smoking any cigar type on a daily basis were less likely to smoke cigarettes (APR = 0.88, 95% CI = 0.78–0.99) than those who did not smoke any cigar type on a daily basis.

Reasons for Using Cigar Products

Socializing when smoking cigars (49.9%–76.6%) and availability of cigars in flavors (48.6%–71.9%) were reasons endorsed by half or more of smokers of all cigar types, while other reasons for use varied by cigar type and cigarette smoking status (Supplementary Table B). Affordability was endorsed by most of those smoking FCs (80.2%), cigarillos (71.7%), and nonpremium cigars (66.4%), but not for those smoking premium cigars (22.7%). More than half of FC smokers overall (52.4%), including 56.2% who also currently smoked cigarettes and 61.0% who formerly smoked cigarettes, indicated FCs were like smoking a regular cigarette, compared with only 6.3%–26.8% of other cigar types.

Table 4. Percent of Dual Cigar and Cigarette Smokers Among Adult Current Established Cigar Smokers and Adjusted Prevalence Ratios by Demographic and Cigar Smoking Characteristics, PATH Study Wave 1, 2013–2014

	Prevalence (95% CI)	Adjusted PR[a] (95% CI)
Smoke premium cigars		
Yes	29.9 (25.5–34.3)	0.52 (0.40–0.67)
No	60.3 (57.2–63.4)	Ref
Smoke nonpremium cigars		
Yes	59.5 (54.6–64.4)	0.97 (0.86–1.09)
No	52.1 (49.0–55.2)	Ref
Smoke cigarillos		
Yes	57.9 (54.4–61.5)	1.09 (0.95–1.25)
No	48.7 (44.9–52.6)	Ref
Smoke filtered cigars (FCs)		
Yes	66.0 (61.3–70.7)	1.23 (1.09–1.39)
No	48.7 (45.9–51.4)	Ref
Use other tobacco products[b]		
Yes	62.1 (57.7–66.4)	1.27 (1.15–1.41)
No	50.4 (47.1–53.7)	Ref
Sex		
Male	51.7 (48.7–54.7)	Ref
Female	59.9 (54.7–65.1)	1.01 (0.91–1.13)
Age group (years)		
18–34	55.1 (51.9–58.4)	0.98 (0.89–1.07)
35+	52.1 (47.8–56.3)	Ref
Race/ethnicity		
White, non-Hispanic	55.2 (51.4–59.1)	Ref
Black/AA, non-Hispanic	49.5 (44.5–54.6)	0.82 (0.72–0.94)
Other/multi-race, or Hispanic	53.0 (47.1–58.9)	0.90 (0.80–1.02)
Education		
GED, HS diploma or less	61.7 (58.5–64.9)	1.20 (1.09–1.33)
Some college/associate degree or more	45.9 (42.2–49.6)	Ref
Daily cigar smoking[c]		
Yes	53.8 (48.4–59.2)	0.88 (0.78–0.99)
No	53.5 (50.5–56.6)	Ref

CI, logit-transformed confidence interval; PR, prevalence ratio; AA, African-American; HS, high school; GED, General Education Development certificate.
[a]There were n = 2045 current established cigar smokers with information on current cigarette smoking status. The regression analysis included n = 1895 participants (n = 834 cigar only; n = 1061 dual cigar + cigarette) after observations missing information for ≥1 covariate were excluded.
[b]Use of other tobacco products defined as having ever used one or more of the following tobacco products "fairly regularly" and now using that product every day or some days: e-cigarettes, pipe tobacco, hookah, smokeless tobacco, snus, or dissolvable tobacco.
[c]Daily cigar refers to smoking at least one cigar type on a daily basis.

Discussion

While historically many research studies and tobacco surveillance systems have treated cigars as a single product type, the PATH Study fills an important gap by providing detailed information on individual user characteristics, tobacco use patterns, purchasing behaviors, and reasons for use separately for traditional cigars, cigarillos, and FCs. Examination by cigar type revealed similarities and differences in demographic and behavioral outcomes. Compared with smokers of traditional-sized premium cigars, those smoking nonpremium cigars tended to be more like cigarillo smokers in demographics, smoking frequency, brand preferences, and purchasing behaviors (eg, price), suggesting nonpremium cigars and cigarillos may be studied jointly in future work. We also found FCs tended to differ from other cigar types including more frequent daily use, greater numbers of cigars smoked per day and older age at first regular use, which, in conjunction with endorsed reasons for use and other measures, suggests that FCs may be smoked in place of cigarettes. Finally, those smoking premium cigars tended to differ from those smoking nonpremium cigars, cigarillos, and FCs including having users with higher socioeconomic status, lower smoking frequency, different purchasing behaviors (eg, where and for how much cigars were bought) and reasons for use.

Several recent studies have examined the characteristics, behaviors, and risk perceptions of LCC smokers.[9–11,26–30,35] Tobacco manufacturers and researchers apply the term "little cigar" interchangeably with FCs, making it difficult to distinguish whether LCC smoking includes use of cigarette-like cigars with filters, larger cigarillo-like unfiltered cigars, or both. Our findings that smokers of FCs tended to differ from cigarillo smokers by frequency and number of cigars per day, age at first use, and the likelihood of cigarette smoking, suggests that future studies should clearly describe the cigar types smoked and differentiate the cigar types analyzed. Despite these notable differences, our results align with prior studies that compared smokers of *any* mass-marketed cigar (eg, users of Black and Milds, Swisher Sweets, Phillies Blunts, Captain Black brands) with traditional large cigar smokers.[9,11,42] Specifically, those who reported smoking nonpremium cigars, cigarillos or FCs tended to be younger, non-Hispanic black, have low educational attainment, live below 200% of the federal poverty line, and smoke cigars on a daily basis as compared with those who smoked premium cigars.

This study is among the first to examine correlates of dual cigar and cigarette smoking *among current cigar smokers*. We found that dual users, relative to cigar-only smokers, were more likely to smoke FCs, use other noncigar/noncigarette tobacco products, and have lower educational attainment. One previous study that assessed factors associated with poly-tobacco use (ie, use of cigarettes, chewing tobacco, or snuff) among cigar smokers also found that poly-use was associated with lower levels of education.[43]

Our findings align and advance prior qualitative work that indicated FCs may be marketed to and smoked by consumers as inexpensive substitutes for cigarettes.[22,23] In adjusted analyses accounting for demographic factors and other tobacco use, only those who reported smoking FCs were significantly more likely to report dual use with cigarettes. Most FC smokers who currently or formerly smoked cigarettes agreed that smoking FCs felt like smoking a regular cigarette. Of note, the median age at first regular use of FCs was nearly a decade older than first regular use of cigarettes, indicating that most FC smokers take up FCs in adulthood rather than during adolescence. Those findings, in conjunction with the median price paid per FC being approximately half that of a cigarette, and high endorsement of affordability as a reason for smoking FCs, add further evidence that FCs may be smoked in place of cigarettes.

This analysis differentiated traditional cigar smokers as either premium or nonpremium based on usual brand and price. Since regulatory definitions of premium cigars do not exist, information about the brand's tobacco blends, components (eg, long filler, whole leaf wrapper), and manufacturing process (eg, handmade), obtained through online searches, was used to distinguish premium from nonpremium brands. Where brand information was unavailable, usual price paid per stick of ≥$2 was applied to identify premium brands, allowing us to classify more smokers than was possible in previous studies.[21] Although the results illustrate clear distinctions between premium and nonpremium smoker characteristics, use patterns and purchasing behaviors, some traditional cigar smokers may have been misclassified using this approach.

Because detailed product use and purchasing questions were asked of those who "*ever fairly regularly*" smoked cigars, this analysis characterizes a population of more established cigar smokers. The adult prevalence of *experimental* cigar smoking (defined as never fairly regularly smoking cigars and now smoking every or some days) was considerably higher than established cigar smoking. Supplementary Table C provides demographic characteristics of *all* adults now smoking cigars every day or some days, irrespective of ever fairly regularly smoking cigars. This broader definition may be more consistent with the population of current cigar smokers that are captured and reported in national tobacco surveys.[38,39]

This study estimated the median number of cigars smoked per day according to each cigar type. It should be noted that the size (ie, weight) of each cigar type varied, which precluded us from making comparisons that standardized the amount smoked for each cigar type. Our understanding of cigar toxicant exposures in general and whether exposures vary according to cigar type will be enhanced through future analyses of PATH Study biomarkers data. Finally, this study did not assess blunt use, whereby part or all of the cigar tobacco filler is replaced with marijuana before it is smoked. Since blunt use can be common among adolescent and adult cigarillo smokers, and in particular, untipped cigarillos users,[15,25,29,44,45] future analyses of cigar smoking behaviors may explore the influence of blunt use among cigarillo subtypes and assess levels of toxicant exposures among blunt and nonblunt users.

While cigars are a combustible tobacco product and carry many of the same health risks as cigarettes, historically, tobacco control policies focused on cigarettes.[14] Our results may be useful to inform tobacco control efforts related to cigar smoking. Most importantly, our data point to adequately describing the cigar type(s) studied, rather than using non-specific terms like "little cigars" or "LCCs," and to differentiating results by cigar type, where appropriate, to enhance tobacco research and surveillance. Our findings that nonpremium cigars, cigarillos, and FCs are more likely to be flavored compared with cigarettes, that FCs had lower median price per stick ($0.12) compared with cigarettes ($0.27), and that usual pack size for cigar smokers is more likely to be a "single" stick compared with cigarettes all highlight product features of cigars that tobacco control and regulatory science research could address. In fact, focus is beginning to shift to noncigarette tobacco products, including cigars.[46–50] For example, New York City, Chicago, and Providence, RI have implemented policies restricting the sale of flavored cigars, while Boston has imposed minimum pack sizes for cigars. Additional tobacco control efforts at local, state, and national levels can reduce the morbidity and mortality associated with use of all cigar types.

Supplementary Material

Supplementary data is available at *Nicotine & Tobacco Research* online.

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Declaration of Interests

Authors do not have any competing interested to report. Additionally, authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Exhibit 23

Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012–2013

Catherine G. Corey, MSPH[1], Brian A. King, PhD[2], Blair N. Coleman, MPH[1], Cristine D. Delnevo, PhD[3], Corinne G. Husten, MD[1], Bridget K. Ambrose, PhD[1], Benjamin J. Apelberg, PhD[1] (Author affiliations at end of text)

The burden of death and disease from tobacco use in the United States has been caused overwhelmingly by cigarettes and other smoked tobacco products (*1*). In the United States, cigarette consumption declined during 2000–2011; however, consumption of cigars more than doubled during the same period (*2*). The cigar market includes diverse product types manufactured with a variety of shapes and sizes, filters, tips, flavors, and prices (*3*). Although national estimates of cigar consumption have been reported previously (*2,3*), data characterizing who smokes different cigar types are limited. A recent analysis from the 2012–2013 National Adult Tobacco Survey (NATS) found that more than one in 20 U.S. adults smoke cigars "every day," "someday," or "rarely" (*4*). This report expands upon those findings, using data from the 2012–2013 NATS to further characterize cigar smokers by the usual type of cigar smoked using the following categories: little filtered cigars (LFCs), cigarillos/other mass market cigars (cigarillos/MMCs), and premium cigars. The findings indicate that among U.S. adults who smoke cigars, 61.8% usually smoke cigarillos/MMCs, 19.9% usually smoke premium cigars, and the remainder, 18.4%, usually smoke LFCs. These data can help to inform public health interventions to reduce the burden of adverse health effects caused by cigar smoking in the United States, including regulation.

The 2012–2013 NATS is a stratified, national, random-digit–dialed landline and cellular telephone survey of 60,192 noninstitutionalized U.S. civilian adults aged ≥18 years. The survey response rate was 44.9% (landline = 47.2%; cell phone = 36.3%). Respondents who now smoked cigars every day, some days, or rarely* were asked the following questions about the attributes of the cigar they usually smoked: 1) "Do you usually smoke a cigar, cigarillo, or little filtered cigar that has…A spongy filter/A plastic tip/A wooden tip/No filter or tip?"; and 2) "What is the name brand of the cigar, cigarillo, or little filtered cigar that you usually smoke?" LFC smokers were defined as those reporting their usual cigar had a spongy filter, or was from a manufacturer that primarily or exclusively manufactures LFCs. Premium cigar smokers were defined as those reporting their usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar (*5*) or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper. Cigarillo/MMC smokers were defined as those reporting their usual cigar did not have a filter and the usual brand was not premium.†

Data were weighted to provide nationally representative estimates. Estimates of usual cigar type among current cigar smokers were calculated overall and by sex, age, race/ethnicity, U.S. Census region,§ education, annual household income, and sexual orientation. Estimates of cigar smoking frequency and cigarette smoking status (former, current, or never cigarette smoker) were calculated by usual cigar type.¶ Estimates with a relative standard error of ≥40% were omitted. Differences between groups were assessed using t-tests ($p<0.05$).

Among the 7.3% of U.S. adults who smoke cigars "every day," "someday," or "rarely," more than half (52.5%) reported information that could be used to assign a usual cigar type. Of these

* Respondents aged ≥30 years had to have reported smoking ≥50 cigars in their lifetime to be asked the questions about cigar attributes, whereas respondents aged 18–29 years did not.

† The 2012–2013 NATS asked a third question about the size of the usual cigar smoked. Whereas respondents who reported using a little filtered cigar or a premium brand tended to report a consistent length for their usual cigar, cigarillo/MMC smokers did not; hence, length information was not used to assign usual cigar type. Among current cigar smokers, 48% could not be assigned a usual cigar type because of insufficient information. Two sources accounted for more than 90% of the missing data. Two thirds not assigned a usual cigar type responded "I do not have a usual size of cigar" to a question about length of the usual cigar smoked and were not asked the cigar filter/tip or brand questions; more than 80% of these users reported smoking cigars rarely. Another 27% reported smoking a cigar that did not have a filter or tip, but did not provide a usual cigar brand, and consequently could not be distinguished as a cigarillo/MMC or premium cigar smoker.

§ *Northeast:* Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont. *Midwest:* Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin. *South:* Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia. *West:* Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

¶ Respondents who reported smoking ≥100 cigarettes in their lifetime and reported now smoking every day or some days were recoded as current cigarette smokers. Respondents aged 18–29 years who reported not smoking ≥100 cigarettes in their lifetime but reported now smoking cigarettes every day or some days were recoded as current smokers. Respondents who reported smoking ≥100 cigarettes in their lifetime and reported now smoking not at all were recoded as former cigarette smokers. Respondents who reported not currently smoking at all and reported not smoking ≥100 cigarettes in their lifetime were recoded as never cigarette smokers.

cigar smokers, 61.8% usually smoke cigarillos/MMCs, 19.9% usually smoke premium cigars, and 18.4% usually smoke LFCs (Table). Cigarillos/MMCs were the usual cigar of most men and most women. Premium cigars were the usual cigar of 23.9% of men, and LFCs were the choice of more women (35.3%) than men (14.5%) ($p<0.05$). Cigarillos/MMCs were the usual cigar of 72.1% of young adults (aged 18–29 years) but were less popular among older adults. However, an estimated 15.1% of persons aged 18–29 years smoked premium cigars, which was comparable to LFCs (12.8%). By race/ethnicity, cigarillos/MMCs were the usual type among cigar smokers who were non-Hispanic black (82.6%), among whom premium cigar smoking was the usual type for only 5.2%. In contrast, among non-Hispanic whites, 26.7% reported premium cigars as their usual choice. In the Northeast, unlike other regions, premium cigars were the usual cigar of more cigar smokers than were LFCs. Higher educational levels and annual household income generally were associated with lower prevalence of usual

TABLE. Selected characteristics of current cigar smokers* aged ≥18 years who identified a usual type of cigar smoked, by usual cigar type — National Adult Tobacco Survey, United States, 2012–2013

	Little filtered cigars†		Cigarillos/MMCs§		Premium cigars¶	
Characteristic	**%**	**(95% CI)**	**%**	**(95% CI)**	**%**	**(95% CI)**
Overall	**18.4**	**(16.1–20.9)**	**61.8**	**(58.6–64.9)**	**19.9**	**(17.4–22.6)**
Sex						
Men	14.5	(12.1–17.2)	61.6	(57.9–65.2)	23.9	(21.0–27.2)
Women	35.3	(28.7–42.4)	59.4	(52.0–66.5)	—††	
Age group (yrs)						
18–29	12.8	(9.8–16.5)	72.1	(67.2–76.5)	15.1	(11.7–19.2)
30–49	18.5	(14.5–23.4)	57.6	(51.6–63.3)	23.9	(19.1–29.5)
50–64	31.7	(26.2–37.8)	43.5	(37.7–49.4)	24.8	(20.4–29.8)
≥65	24.0	(17.5–32.1)	55.6	(46.8–64.1)	20.4	(14.6–27.7)
Race/Ethnicity						
White, non-Hispanic	20.2	(17.2–23.6)	53.1	(48.9–57.2)	26.7	(23.2–30.5)
Black, non-Hispanic	12.2	(7.5–19.3)	82.6	(74.8–88.3)	5.2	(2.5–10.4)
Other, non-Hispanic	22.5	(16.3–30.2)	68.4	(60.2–75.6)	9.1	(5.8–14.1)
Hispanic	14.7	(8.4–24.4)	65.9	(54.0–76.0)	19.5	(11.5–30.9)
U.S Census region**						
Northeast	13.9	(9.7–19.7)	57.6	(48.2–66.4)	28.5	(20.4–38.3)
Midwest	20.2	(15.5–25.9)	65.2	(58.7–71.2)	14.6	(10.8–19.6)
South	16.3	(13.1–20.2)	64.8	(59.9–69.3)	18.9	(15.5–22.9)
West	23.1	(17.3–30.1)	57.0	(49.7–64.0)	19.9	(15.4–25.2)
Education						
0–12 years (no diploma)	23.6	(16.8–32.0)	73.1	(64.2–80.4)	—††	
High school diploma or GED	19.0	(14.9–24.0)	69.8	(63.7–75.3)	11.1	(7.3–16.6)
Some college or associate degree	20.5	(16.5–25.0)	57.1	(51.6–62.4)	22.5	(18.1–27.5)
Undergraduate degree or higher	8.0	(5.3–11.8)	40.3	(34.6–46.3)	51.7	(45.8–57.6)
Annual household income ($)						
<20,000	34.6	(27.5–42.5)	60.6	(52.5–68.1)	4.8	(2.5–8.9)
20,000–49,999	17.6	(13.7–22.2)	71.5	(66.0–76.5)	10.9	(7.8–15.1)
50,000–99,999	12.1	(8.5–17.1)	60.9	(53.8–67.5)	27.0	(21.3–33.6)
≥100,000	10.1	(6.0–16.6)	49.9	(41.8–58.0)	40.0	(32.4–48.1)
Unspecified	21.0	(15.5–28.0)	58.3	(50.4–65.8)	20.7	(14.8–28.2)
Sexual orientation						
Heterosexual/Straight	17.6	(15.2–20.2)	61.5	(58.0–64.9)	20.9	(18.2–23.9)
Lesbian, gay, bisexual	35.6	(22.5–51.2)	51.9	(36.8–66.6)	12.5	(5.8–25.0)
Unspecified	18.1	(11.6–27.2)	67.0	(56.6–76.0)	14.9	(8.5–24.8)

Abbreviations: CI = confidence interval; MMC = mass market cigar; GED = General Education Development certification.

* To be eligible to be assigned a usual cigar type, respondents had to now smoke cigars "every day," "some days," or "rarely"; in addition, adults aged ≥30 years had to report smoking ≥50 cigars in their lifetime, whereas adults aged 18–29 years did not.

† Respondent reported their usual cigar had a spongy filter, or was from a manufacturer that primarily or exclusively manufactures little filtered cigars. Respondents who smoked little filtered cigars but usually smoked another type are not included.

§ Respondent reported their usual cigar did not have a filter and the usual brand was not premium. Respondents who smoked cigarillos/other mass market cigars but usually smoked another type are not included.

¶ Respondent reported their usual cigar did not have a filter or tip, and the name of the usual brand was identified as being hand-rolled or otherwise described as containing high-grade tobaccos in the filler, binder, or wrapper. Respondents who smoked premium cigars but usually smoked another type are not included.

** *Northeast*: Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont. *Midwest*: Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin. *South*: Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia. *West*: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

†† Estimate not presented because relative standard error ≥40%.

use of cigarillos/MMCs and of LFCs, and higher prevalence of usual use of premium cigars. By sexual orientation, prevalence of LFCs as a usual cigar was greater among lesbian, gay, and bisexual adults (35.6%) than among heterosexual/straight adults (17.6%) ($p<0.05$).

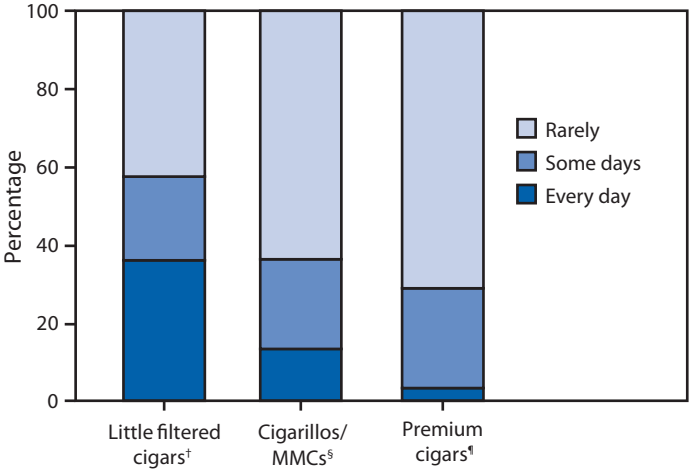
Among cigar smokers who usually smoked premium cigars, 3.3% reported "every day" use, 25.6% reported "some day" use, and 71.2% reported use "rarely" (Figure 1). Among usual smokers of cigarillos/MMCs, 13.3% reported "every day" use, 23.0% reported "some day" use, and 63.8% reported use "rarely." Among usual smokers of LFCs, 36.0% reported "every day" use, 21.5% reported "some day" use, and 42.5% reported use "rarely."

Among usual smokers of premium cigars, 35.1% currently smoked cigarettes, 23.0% formerly smoked cigarettes, and 41.9% never smoked cigarettes (Figure 2). Among usual cigarillo/MMC smokers, 58.3% currently smoked cigarettes, 15.3% formerly smoked cigarettes, and 26.4% never smoked cigarettes. Among usual LFC smokers, 75.2% smoked cigarettes, 12.3% formerly smoked cigarettes, and 12.4% never smoked cigarettes.

Discussion

On the basis of these results, it is estimated that three in five cigar smokers (an estimated 10.9 million persons) usually smoke cigarillos/MMCs, approximately one in five (an estimated 3.6 million persons) usually smoke premium cigars, and nearly one in five (an estimated 2.9 million persons) usually smoke LFCs. Younger adults were more likely to identify cigarillos/MMCs as their usual cigar (72.1% of cigar smokers). However, among those aged 18–29 years, 15.1% reported that their usual cigar was a premium cigar; 12.7% usually smoked LFCs. Additionally, variations in usual cigar type by sex, age, race/ethnicity, education, income, and sexual orientation suggest that a single, aggregated measure of cigar smoking might mask important differences in tobacco use behaviors. For example, more than eight in 10 cigar smokers who were non-Hispanic black used cigarillos/MMCs. More disaggregated surveillance by cigar type has the potential to better inform public health strategies to reduce the health burden of cigar smoking in the United States. Regular cigar use is estimated to be responsible for approximately 9,000 premature deaths and almost 140,000 years of potential life lost annually, and this might underestimate total

FIGURE 1. Percentage of current cigar smokers aged ≥18 years who smoke cigars every day, some days, or rarely, by type of cigar usually smoked — National Adult Tobacco Survey, United States, 2012–2013



Abbreviation: MMC = mass market cigar.

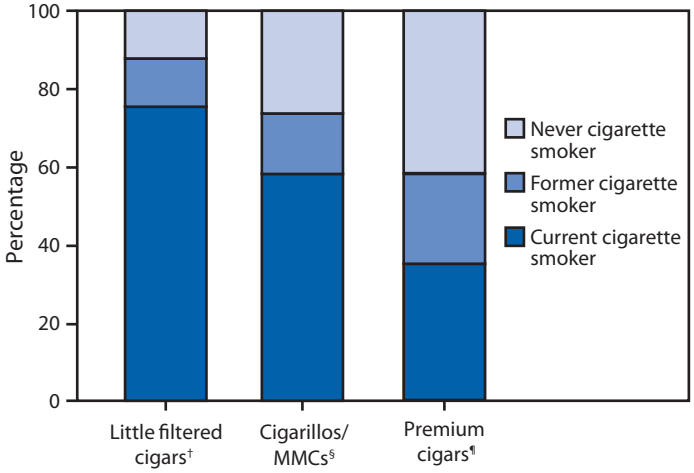
* To be eligible to be assigned a usual cigar type, respondents had to currently smoke cigars "every day," "some days," or "rarely"; in addition, adults aged ≥30 years had to report smoking ≥50 cigars in their lifetime, whereas adults aged 18–29 years did not.

† Respondent reported their usual cigar had a spongy filter, or was from a manufacturer that primarily or exclusively manufactures little filtered cigars.

§ Respondent reported their usual cigar did not have a filter and the usual brand was not premium.

¶ Respondent reported their usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper.

FIGURE 2. Percentage of current cigar smokers aged ≥18 years who currently smoke cigarettes, formerly smoked cigarettes, or never smoked cigarettes, by type of cigar usually smoked — National Adult Tobacco Survey, United States, 2012–2013



Abbreviation: MMC = mass market cigar.

* To be eligible to be assigned a usual cigar type, respondents had to currently smoke cigars "every day," "some days," or "rarely"; in addition, adults aged ≥30 years had to report smoking ≥50 cigars in their lifetime, whereas adults aged 18–29 years did not.

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What is already known on this topic?

The cigar market includes diverse product types manufactured with a variety of shapes and sizes, filters, tips, flavors, and prices. Although national estimates of cigar consumption have been reported previously, data characterizing who uses different cigar types are limited.

What is added by this report?

Among current cigar smokers who provided information that could be used to assign a usual cigar type, 61.8% usually smoke cigarillos/other mass market cigars, 19.9% usually smoke premium cigars, and the remainder, 18.4%, usually smoke little filtered cigars. Variations in usual cigar type were observed by sex, age, race/ethnicity, education, household income, and sexual orientation. Daily cigar smoking was reported by 3.3% of usual premium cigar smokers, 13.3% of usual cigarillo/other mass market cigar smokers, and 36.0% of usual little filtered cigar smokers. Among each group of smokers, nearly 60% or more of current cigar smokers are either current or former cigarette smokers; these persons are more likely to inhale cigar smoke more deeply, putting them at particularly high risk for tobacco-related diseases.

What are the implications for public health practice?

Enhanced monitoring of noncigarette product use, including use of different cigar types and concurrent use of multiple tobacco products, can inform efforts to reduce the burden of adverse health effects caused by cigar smoking in the United States.

premature mortality because deaths resulting from less frequent cigar smoking were not estimated (*6*). These findings underscore the importance of public health interventions to reduce cigar smoking among U.S. adults. Evidence-based tobacco control interventions such as increased taxes, smoke-free policies, and public education campaigns should also address noncigarette tobacco products.

Daily cigar smoking was reported by 3.3% of usual premium cigar smokers, 13.3% of usual cigarillo/MMC smokers, and 36.0% of usual LFC smokers, suggesting that cigar smoking is not exclusively an infrequent or rare behavior. Regardless of cigar type, nearly 60% or more of current cigar smokers are either current or former cigarette smokers. Cigar smokers that are current or former cigarette smokers are more likely to report inhaling cigar smoke, putting them at particularly high risk for tobacco-related diseases (*7*). Even cigar smokers who report not inhaling show evidence of inhalation (*8*). Moreover, elevated risks for dying from oral, pharyngeal, laryngeal, and esophageal cancers have been found among those reporting no inhalation (*7*). The high proportion of current and former cigarette smoking reported by current cigar smokers underscores the importance of continued implementation of proven, population-based interventions to address all forms of tobacco use, especially smoked products such as cigarettes and cigars that currently account for the greatest public health burden in the United States (*1*).

The findings in this report are subject to at least six limitations. First, cigar use was self-reported and not biochemically verified; however, self-reported cigarette smoking correlates highly with serum cotinine levels, suggesting good validity of self-reported cigar use (*9*). Second, more than 47% of current cigar smokers could not be assigned a usual cigar type because of insufficient information about the usual cigar smoked; to generate weighted counts of cigar smokers by cigar type, the distribution of usual type was assumed to be the same for those with and without missing information, after controlling for frequency of use. Third, for each type of cigar, data were gathered only from persons who smoked them as their usual cigar; persons who smoked more than one type of cigar contributed data only for their usual cigar type. Fourth, price or cigar weight could also be used to differentiate cigar types; however, NATS did not collect data for either. Fifth, small sample sizes for certain subgroups resulted in less precise estimates. Finally, the NATS response rate of 44.9% might have resulted in nonresponse bias, even after adjustment for nonresponse. Although they are not limitations, it is important to note two features of the 2012–2013 NATS. First, a response option of "rarely" was provided to characterize cigar smoking frequency after cognitive testing suggested some cigar smokers did not consider "every day," "some days," or "not at all" to accurately reflect their use; however, although respondents chose this option to describe their current use of cigars, exactly how respondents interpreted "rarely" is unknown. In addition, the approach used to assign usual cigar type differed from that of another national tobacco survey, which asked cigar smokers to report their usual cigar type as either LFC, cigarillo, or regular/large cigar, thus yielding potentially different distributions of cigar smokers according to usual cigar type (*10*).

In April 2014, the Food and Drug Administration proposed to extend its jurisdiction over the manufacture, marketing, and sale of tobacco products to cigars.** Full implementation of comprehensive tobacco control programs at CDC-recommended funding levels could reduce all forms of tobacco use, including cigars, and change social norms regarding the acceptability of tobacco use in the United States.†† Additionally, given the diversity of tobacco product use in the United States (*4*), enhanced surveillance of noncigarette products, including different cigar types and concurrent use of multiple tobacco products, is critical.

** Additional information available at http://www.fda.gov/aboutfda/reportsmanualsforms/reports/economicanalyses/ucm394922.htm.

†† Additional information available at http://www.cdc.gov/tobacco/stateandcommunity/best_practices.

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[1]Center for Tobacco Products, Food and Drug Administration; [2]Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, CDC; [3]Center for Tobacco Studies, Rutgers School of Public Health (Corresponding author: Catherine Corey, catherine.corey@fda.hhs.gov, 301-796-7396)

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