Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION:

A. Legal Authority

HHS/CDC is promulgating this policy under the authority of sections 201–204 and 221 of Title II of Public Law 107–188, 116 Stat 637 (42 U.S.C. 262a).

B. Background

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act) (42 U.S.C. 262a(a)(1)), the HHS Secretary regulates a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The biological agents and toxins listed in 42 CFR 73.3 (HHS select agents and toxins) have the potential to pose a severe threat to human health and safety and are regulated only by HHS/CDC. The biological agents listed in § 73.4 (overlap select agents and toxins) have not only the potential to pose a severe threat to human health and safety; but have been determined by the USDA, pursuant to USDA's authority under the Agriculture Bioterrorism Protection Act of 2002 (7 U.S.C. 8401), to have the potential to pose a severe threat to animals and animal products. Accordingly, these biological agents are jointly regulated by HHS/CDC and USDA as ''overlap'' select agents. The Bioterrorism Response Act defines the term ''overlap agent or toxin'' to mean a biological agent or toxin that is listed pursuant to 42 U.S.C. 262a and is listed pursuant to 7 U.S.C. 8401. See 7 U.S.C. 8411.

Brucellosis, also known as contagious abortion or Bang's disease, is a contagious, costly disease that has significant animal health, public health, and international trade consequences. While most often found in ruminant animals (*e.g.,* cattle, bison, cervids and swine), brucellosis can affect other animals and is transmissible to humans. Brucellosis is caused by a group of bacteria known scientifically as the genus *Brucella.* Two species of *Brucella* found in the United States: *B. abortus,* principally affecting cattle, bison, and cervids, and *B. suis,* principally affecting swine and reindeer, but also cattle and bison.

Brucellosis can be costly to agriculture production. In 1952, prior to established efforts to eradicate the disease, agriculture production losses due to brucellosis exceeded $400 million. A cautionary indicator of the need for greater understanding of the disease is the expanding range of endemic *B. abortus* in the Greater Yellowstone Area and *B. suis* in feral swine populations throughout various areas of the United States. This disease expansion emphasizes the critical need for improved diagnostics, along with vaccine development for both *Brucella* species, which could be furthered by outdoor research studies.

Both *B. abortus* and *B. suis* are currently listed as overlap select agents in select agent regulations (42 CFR 73.4 and 9 CFR 121.4). Accordingly, any outdoor research studies must comport with the select agent and toxin regulations. Therefore, HHS/CDC and USDA are issuing a FSAP draft policy statement on biosafety for large animal outdoor containment studies with *B. abortus* and *B. suis* to aid individuals and entities in the development of biosafety plans for such studies that meet the requirements of the select agent regulations. We are making this policy document available to the public at the Supporting & Related Materials tab of the docket and at *https://www.selectagents.gov/regulations/policy/animalstudy.htm* for review and comment.

Copies of the policy document are also available for public inspection at USDA, room 1620, South Building, 14th Street and Independence Avenue SW, Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799–7039 to facilitate entry into the reading room. In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2021–00877 Filed 1–14–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0002]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment. The meeting will be webcast live via the World Wide Web.

DATES: The meeting will be held on January 27, 2021 from 10:00 a.m. to 5:00 p.m., EST (times subject to change, see the ACIP website for any updates: *http://www.cdc.gov/vaccines/acip/index.html*).

Written comments must be received on or before January 27, 2021.

ADDRESSES: For more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

You may submit comments, identified by Docket No. CDC–2021–0002 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket No. CDC–2021–0002, c/o Attn: January 27, 2021 ACIP Meeting, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, GA 30329–4027.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

Written public comments submitted 24 hours prior to the ACIP meeting will be provided to ACIP members before the meeting.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, GA 30329–4027; Telephone: 404–639–8367; Email: *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency.

Purpose: The committee is charged with advising the Director, CDC, on the

use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters to be Considered: The agenda will include discussions on COVID–19 vaccines. No recommendation vote is scheduled for COVID–19 vaccines. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials are part of the public record and are subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket. CDC does not accept comment by email.

Written Public Comment: Written comments must be received on or before January 27, 2021. Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the January 27, 2021 ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EST, January 25, 2021 according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by January 26, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–00870 Filed 1–12–21; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2306]

TG United Inc., et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 27 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040083	Phentermine Hydrochloride (HCl) Capsules, 30 milligrams (mg)	TG United Inc., 16275 Aviation Loop Dr., Brooksville, FL 34604.
ANDA 040451	Cyanocobalamin Injection, 1 mg/milliliters (mL)	Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
ANDA 040518	Bethanechol Chloride Tablets, 50 mg	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC, 6451 W. Main St., Morton Grove, IL 60053.
ANDA 040532	Bethanechol Chloride Tablets, 5 mg	Do.