Interim Guidance - Expedited Review for Products Adding Residual Efficacy Claims

EPA is announcing the expedited review of certain applications for registration and amended registration for products intended for use against the SARS-CoV-2, the novel human coronavirus that causes COVID-19. Pursuant to Title VII of the CARES Act passed on March 27, 2020, EPA is providing notice of its intention to expedite reviews for addition of residual (i.e., extended or long-lasting) efficacy claims for currently registered or new product registrations that are on EPA's Disinfectant List N, that would qualify for List N, or products that can be used as a residual supplement to disinfectants on List N.

Under the Pesticide Registration Improvement Act (PRIA), typical decision review timeframes for these types of registration actions range from four months for amendments and new registrations for products similar to existing products, to 24 months for new active ingredient submissions (AD PRIA Action Code Tables). For antimicrobial products that may be of use against SARS-CoV-2, EPA is currently making every effort to expedite the review and make regulatory decisions for the submissions discussed in this document by at least one to two months faster than the normal PRIA timeframe, depending on the submission, provided the procedures described in this interim guidance are followed. This is consistent with EPA's previous guidance for expedited review. As EPA gains more experience with expedited procedures, we may revise the expected completion timeframes for these actions.

Recently, there has been increased interest in obtaining residual efficacy claims (i.e., claims that a product provides an ongoing antimicrobial effect beyond the initial time of application, ranging from days to weeks to months). Traditional liquid-based antimicrobials (e.g., List N disinfectants) treat the surface at the time of application but do not provide efficacy beyond the time of application. There is significant desire from stakeholders and the public for products that are continuously active and can provide efficacy in between regular cleaning and disinfection. These products may reduce the level of re-contamination on high touch surfaces.

Accordingly, EPA will expedite review of the applications for amended registrations and new registrations that do not include a new active ingredient for the residual effect claims listed in the table immediately below. Applicants need to be aware, however, that in order to expedite these submissions, it is necessary for EPA to receive all of the information specified in this document. To the extent that EPA does not receive the identified information, EPA may not be able to process these submissions in an expedited fashion. In any such cases, EPA may default to the PRIA timeframe otherwise associated with the submission after consultation with the registrant.

Products with residual effect claims that qualify for this expedited review fall into two major categories; (1) disinfectants that also provide residual efficacy, and (2) supplemental residual antimicrobial products (e.g., coatings, paints, solid surfaces) that do not meet EPA's standards for disinfectants but are intended to be used as a supplement to standard List N disinfectants.

Note that depending on their intended use, some antimicrobial products may be subject to both EPA and FDA jurisdiction (e.g., liquid chemical disinfectants and devices used to disinfect health care facilities and non-critical medical devices), and therefore may require FDA review. Other products may be subject to FDA's exclusive jurisdiction (e.g., liquid chemical disinfectants and devices used against microorganisms in or on humans or other animals, liquid chemical sterilants for use on a critical or semi-critical medical devices) and are outside the scope of this guidance.

Below is a summary table and key attributes for these two different types of residual claims.

	Claim		
	Residual Disinfectants	**Supplemental Residual Antimicrobial Products**	
		Coatings & Films	**Fixed (Solid & Paints)**
Meets EPA's standard for disinfection efficacy	Yes	No	No
Duration of residual claim	≤ 24 hours	Weeks (product efficacy determines duration)	Years
Durability assessment	Abrasion	Abrasion & Chemical	Abrasion & Chemical
Performance standard for bacteria for residual claim	5-log reduction	3-log reduction	3-log reduction
Performance standard for viruses* for residual claim	3-log reduction	3-log reduction	3-log reduction
Time to meet performance standard	≤ 10 minutes	≤ 2-hours	≤ 2-hours

* Claims for viruses can only be added if the product has also met the performance standard for bacteria. This is described in further detail below.

A full description of these two types of claims and the efficacy testing to support these claims is included below. While EPA does not have an approved standard method to support virus claims for these types of products, the following is intended to provide interim guidance on the study design elements necessary to support these types of claims. Note that EPA may consider other methods or studies to support residual efficacy claims, provided they are scientifically sound. Applicants are highly encouraged to consult with EPA prior to submitting. Note that products may make both types of residual claims provided that they are supported by the appropriate data.

Due to lab capacity concerns, non-GLP (Good Laboratory Practice) data will be considered to support residual claims, provided that the study submission accurately represents how the study differs from the GLP standards in the 40 CFR 160.12 statement of non-compliance.

Residual Disinfectant Claims

I. **Qualifying products must satisfy all requirements for standard disinfectant claims (non-residual) in order to be eligible for residual disinfectant claims and have undergone testing to support standard disinfectant claims.**[1]

II. **To support a claim as a residual bactericidal disinfectant utilize EPA's Residual Self-Sanitization Protocol with the following modifications to support residual disinfectant claims:**

- Base Bacteria—Consistent with EPA Guideline 810.2200, *Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442) should be used to support the case residual disinfectant claim.
- Conduct testing on 3 product lots at the lower certified limit (LCL) for each bacterium. In accordance with the OCSPP 810.2000 Test Guideline, certificates of analysis should be submitted to substantiate the tested concentration;
- Residual testing to support additional vegetative bacteria is not needed. Claims can be bridged from the standard disinfectant (non-residual data) for additional bacteria. For example, if a product has data to support a base disinfectant claim (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and data to support disinfectant claims for additional vegetative bacteria (e.g., *E. coli* or MRSA), residual data are only needed for the base bacteria and not additional bacteria in order to support residual claims for those vegetative bacteria for which base disinfectant claims are supported.
- Per the Residual Self-Sanitization Method, durability testing should include 12 wear cycles consisting of abrasions (alternating wet and dry) and re-inoculations to support a 24-hour residual disinfectant claim. Each wear cycle consists of 4 passes (2 back and forth) of the abrasion material over the surface followed by re-inoculation. Additional details can be found in the method.
- Products should achieve a ≥ 5-log reduction in ≤ 10 minutes ± 5 seconds for qualifying bacteria when compared to the parallel abrasion and re-inoculation controls to support residual disinfectant claims.
    - Per the OCSPP 810.2200 Test Guideline, the performance standard and time to meet the performance standard are consistent with the standards for non-residual disinfectants.
- At this time, expedited review is limited to residual disinfection claims of 24 hours or less based on data generated in accordance with the re-inoculation and abrasion cycles specified in the referenced protocol.

[1] This standard disinfectant testing must be conducted in accordance with the OCSPP 810.2200 Product Performance Test Guideline for each organism (vegetative bacteria and virus) for which residual claims are being requested. Per the 810.2200 Test Guideline, testing to support a base disinfectant (non-residual) claim should utilize the AOAC Use Dilution Method, Germicidal Spray Test, or Germicidal Spray Test modified for towelettes as appropriate. Testing should be conducted against *Staphylococcus aureus (S. aureus) and Pseudomonas aeruginosa (P. aeruginosa)*. Testing to support a virucidal (non-residual) claim should utilize ASTM E1053. The performance standards for each organism and product type are specified in the test guideline. Data to support both residual and non-residual disinfectant claims can be submitted and reviewed concurrently. Stand-alone residual disinfectant (e.g., products with only residual claims) claims are not permitted. In addition, data for residual bactericidal claims are needed before residual virucidal claims can be added.

A. Residual Virucidal Claims

Utilize EPA's Residual Self-Sanitization Protocol with the modifications below to support residual virucidal claims. Virucidal efficacy should be assessed consistent with the principles of ASTM E1053 (e.g., recovery, cytotoxicity, neutralization, calculations); the standard virucidal method detailed in OCSPP 810.2200 Product Performance Test Guideline

- To support residual virucidal claims, acceptable non-residual virucidal efficacy (3-log reduction) should be demonstrated for the product at ≤10-minute contact time consistent with the OCSPP 810.2200 Product Performance Test Guideline.
- Residual virucidal data should be generated for the most difficult to kill virus that you are claiming to kill. Claims for residual effect against the other viruses can be bridged from the non-residual virucidal data supporting your product. For additional information on selecting the most difficult to kill virus, see EPA's Emerging Viral Pathogens Guidance.
    - Note that to be considered for List N, virus testing should include a non-enveloped virus or a human coronavirus (SARS-CoV-2 or human coronavirus 229E).
- Conduct testing on 2 product lots at the LCL.
- Per the Residual Self-Sanitization Method, durability testing should include 12 wear cycles consisting of abrasions (alternating wet and dry) and re-inoculations to support a 24-hour residual disinfectant claim. Each wear cycle consists of 4 passes of the abrasion material over the surface followed by re-inoculation. Additional details can be found in the method.
- Products should achieve ≥ 3-log reduction in ≤ 10 minutes ± 5 seconds for the hardest to kill virus when compared to the parallel abrasion and re-inoculation controls to support residual virucidal claims.
    - The performance standard and contact times are consistent with the standard non-residual disinfectants.
- At this time, expedited review is limited to residual disinfection claims of 24 hours or less based on data generated in accordance with the re-inoculation and abrasion cycles specified in the referenced protocol.

B. Residual Disinfectant Claims - Labeling and Additional Information

- Products are eligible for inclusion on List N following adherence to the Emerging Viral Pathogens guidance or appropriate testing for a qualifying virus (e.g., SARS-CoV-2 or Human Coronavirus 229E).
- These products can be used as stand-alone disinfectants and do not need a label disclaimer that they are a "supplement to standard disinfection" since they meet the general criteria for disinfectants (effective in ≤ 10 minutes with appropriate log reductions for bacteria and virus).

Supplemental Residual Antimicrobial Products

III. **Qualifying antimicrobial surface coatings, films, fixed/solid and paint products should demonstrate efficacy against vegetative bacteria first before virus claims can be supported. These products are not required to meet the efficacy standards for disinfectants and can only be approved for use as supplements to standard disinfection. The duration of residual effectiveness claims that EPA will consider for expedited review depends on the type of product as detailed below.**

A. Antimicrobial Surface Coatings and Films

Utilize EPA's draft Performance of Antimicrobial Surface Coatings on Hard Non-porous Surfaces for qualifying bacteria. Additional information is provided below for addition of virus claims.

- Test Organisms
  - Bacteria—*Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442) are the qualifying bacteria required to support supplemental residual antimicrobial surface claims for the proposed claim duration (e.g., 1 week, 2 weeks, etc.)
    - Testing should be conducted on 3 product lots per bacterium at the LCL.
  - To support claims for additional bacteria, testing should be conducted according to the method but with a reduced number of product lots.
    - 2 lots of product for each bacterium at the nominal concentration.
  - Viruses—All viruses for which claims are desired should be tested. The most difficult to kill virus should be subjected to the durability assessment using coating carriers followed by the efficacy assessment to support the proposed duration (e.g., 1 week, 2 weeks, etc.). All other viruses should be tested using coated carriers that were not subjected to the durability procedure.
    - Assessment of virucidal efficacy on the coated carriers should be conducted consistent with ASTM E1053, the standard method specified in EPA's 810.2200 Efficacy Test Guideline.
    - Two lots of product at the LCL should be tested for the most difficult to kill virus. Two lots of product at the nominal concentration should be tested for additional viruses.
      - Note that to be considered as a supplement to List N, virus testing should include a non-enveloped virus or a human coronavirus (SARS-CoV-2 or human coronavirus 229E).
- Stainless steel carriers will be used to support claims for coatings on hard, nonporous surface. Use sites should be limited to hard, non-porous surfaces. Additional material types (e.g., porous materials or textiles) may be proposed by the registrant upon consultation with EPA prior to submission.
- The recommended number of abrasions (touches) and cycles of exposure to cleaning or disinfecting chemicals are provided in the method in order to substantiate durability claims. The method also specifies the chemical disinfecting solutions to simulate cycles of in-service disinfection and cleaning. Additional details can be found in the method.
    - 10 cycles of abrasion/chemical exposure = 1 week of durability. The number of cycles can be increased in 1 week increments to support claims up to 4-weeks.

    - If a product is incompatible with one or more of the test chemistries, this should be discussed with EPA in advance and may limit use sites and surfaces depending on the nature of the incompatibility. EPA does not have a standard method for determining incompatibility. This may be based on research and development data or known incompatibilities with the coating material for example.
- This protocol can be modified for films upon consultation with EPA in advance of submission.
- If you intend to claim supplemental residual effects longer than 4-weeks, consult with EPA in advance of submission. Because the on-going antimicrobial integrity of coatings and films will not be readily visible, it is important that end users have a reasonable expectation of durability.
- Products should achieve a 99.9% reduction (3-log) for both bacteria and virus/es in comparison to untreated controls within a maximum of 2-hours but not less than 1-hour, as EPA is concerned that observations taken before the inoculum has dried (e.g., less than 1 hour) on the surface may not provide an accurate assessment of the product.
    - The time to achieve performance begins at the time of inoculation.

B. Antimicrobial Surface Coatings and Films - Labeling and Additional Information

This new category of antimicrobial products should be labeled as supplemental residual antimicrobial surfaces.

- As these products do not meet the criteria for a disinfectant due to the longer contact time and lower performance standard, claims for residual disinfectant are not acceptable. As above, contact times for disinfectants are ≤ 10 minutes and with a higher performance standard for bacteria.
- Products should carry the following prominent label qualifier that they are a supplement to standard disinfection and cleaning:
    - "Although this product DOES NOT meet EPA's standards for disinfectants, EPA has determined that, when used with an EPA-registered disinfectant, this product can provide some additional protection against [microorganism(s)] for up to X days. This product DOES NOT achieve the same level of efficacy as an EPA-registered disinfectant; it is only intended to provide supplemental protection between routine applications of EPA-registered disinfectants."
- For products eligible only for supplemental residual antimicrobial claims, EPA intends to require as a term of registration that the label and labelling state "This product does not meet EPA's efficacy standards to qualify as a stand-alone disinfectant".
- Although these products will not be eligible for List N, they will be eligible as a supplement to List N (N.1) to reflect that they are supplemental treatments (i.e., not stand-alone disinfectants) and intended for use in combination with List N disinfectants.
- The following are example acceptable product label claims:
    - "Kills 99.9% of [insert microorganism/s] within 2 hours of exposure when used as part of a comprehensive infection control program/protocol for up to X days."
    - "Continuously reduces [insert microorganism/s] within 2 hours of exposure when used as part of a comprehensive infection control program for up to X days."

C. Fixed/Solid Surfaces Including Solid Copper and Other Metals and Solid Impregnated Materials and Paints- Method Recommendation

Utilize EPA's Finalized Copper Surface Protocol for qualifying bacteria. Additional information is provided below for addition of virus claims.

- Test Organisms
    - Bacteria—*Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442) are the qualifying bacteria used to support supplemental residual surface claims.
        - Testing should be conducted on 3 product lots per bacterium at the LCL.
    - To support claims for additional bacteria, testing should be conducted according to the method but with a reduced number of product lots.
        - 2 lots of product for each bacterium at the nominal concentration.
    - Viruses—All viruses for which claims are desired should be tested. The most difficult to kill virus should be subjected to the durability assessment in the copper method followed by the efficacy assessment. All other viruses should be tested using test carriers that were not subjected to the durability procedure.
        - Assessment of virucidal efficacy on the coated carriers should be conducted consistent with ASTM E1053, the standard method specified in EPA's 810.2200 Efficacy Test Guideline
        - Two lots of product at the LCL should be tested for the most difficult to kill virus. Two lots of product at the nominal concentration should be tested for additional viruses.
- The recommended number of abrasions (touches) and cycles of exposure to cleaning or disinfecting chemicals are provided in the method in order to substantiate durability claims. The method also specifies the chemical solutions to simulate cycles of disinfection and cleaning.
    - As the durability of these types of product can be readily observed, duration claims are not necessary. This is consistent with currently registered copper-containing surface products and paints.
    - If a product is incompatible with one or more of the test chemistries, this should be discussed with EPA in advance and may limit use sites and surfaces depending on the nature of the incompatibility. EPA does not have a standard method for determining incompatibility. This may be based on research and development data or known incompatibilities with the coating material for example.
- This protocol can be modified for other metals or solid impregnated surfaces or paints upon consultation with EPA.
- Products should achieve a 99.9% reduction (3-log) for both bacteria and virus/es in comparison to untreated controls within 2-hours.
    - The time to achieve performance begins at the time of inoculation.

D. Fixed/Solid Surfaces Including Solid Copper and Other Metals and Solid Impregnated Materials and Paints - Labeling and Additional Information

These products should be labeled as supplemental residual antimicrobial surfaces.

- As these products do not meet the criteria for a disinfectant due to the longer contact time and lower performance standard, claims for residual disinfectant are not acceptable.
- Products should carry the following prominent label qualifier that they are a supplement to standard disinfection and cleaning:
    - "Although this product DOES NOT meet EPA's standards for disinfectants, EPA has determined that, when used with an EPA-registered disinfectant, this product can provide some additional protection against [microorganism(s)] for up to X days. This product DOES NOT achieve the same level of efficacy as an EPA-registered disinfectant; it is only intended to provide supplemental protection between routine applications of EPA-registered disinfectants."
- For products eligible only for supplemental residual antimicrobial claims, EPA intends to require as a term of registration that the label and labelling should state "This product does not meet EPA's efficacy standards to qualify as a stand-alone disinfectant".
- Although these products will not be eligible for List N, they will be eligible as a supplement to List N (N.1) to reflect that they are supplemental treatments (i.e., not stand-alone disinfectants) and intended for use in combination with List N disinfectants. The following are example acceptable product label claims:
    - "Kills 99.9% of [insert microorganism/s] within 2 hours of exposure when used as part of a comprehensive infection control program/protocol"
    - "Continuously reduces [insert microorganism/s] within 2 hours of exposure when used as part of a comprehensive infection control program"

E. Supplemental Residual Antimicrobial Products - Stewardship Program

EPA intends to require, as a term of registration, that registrants of all supplemental residual antimicrobial products prepare and implement a written stewardship plan designed to support the responsible use of supplemental residual coatings and antimicrobial surface products. Unlike the conventional antimicrobial products, these products represent unique challenges that require timely feedback to ensure proper use and compatibility in combination with current infection control practices. EPA expects that plans would be submitted for EPA review and approval during the registration process, or shortly thereafter (e.g., within two months after the registration date). An approvable plan would address the proper sale (including advertising and promotional materials), distribution, and responsible use of the supplemental residual coatings and antimicrobial surface products. Plans should include, at a minimum, the following elements:

- Advertising and promotional materials that clearly and consistently include a disclaimer that the product does not meet EPA's standards for disinfectants and is intended to supplement the use of EPA-registered disinfectants.
- Outreach to the infection control community;

- Customer feedback consisting of product issues/concerns, adverse events, compliance challenges/observations, and contraindications/adverse events gathered through quarterly registrant-initiated surveys, customer complaints, and suggestion boards; and
- Development of a stewardship website

If EPA determines at any time following registration that the Plan is not being adequately or timely implemented or does not effectively ensure the product's safe and effective use, the registration may be cancelled by the Agency.

How to Prepare an Application for Registration

1. Requests to Amend Currently Registered Products That Require the Review of Data Under PRIA:

A. Residual Disinfectants

Submission of new efficacy data to add residual disinfectant claims to an already EPA-registered product can be submitted as a PRIA A570 action for expected expedited review. EPA will make every effort to complete the review and make a regulatory decision one to two months faster than the standard four-month timeframe under PRIA. EPA will consider expedited review of applications for amended registration to add residual disinfection claims for use under the following situations:

i. If the currently registered product labeling is approved only for sanitizer claims or the labeling is approved with no public health claims, the following data should be submitted for EPA to consider approving residual virucidal claims:

   As described above in section I and II, efficacy data to support a base (non-residual) disinfection claim (*Staphylococcus aureus* and *Pseudomonas aeruginosa*, see OCSPP 810.2200 for details) and non-residual virus data for all viruses for which residual claims for viruses are being requested. In order to qualify for expedited review, at least one of the viruses should be a non-enveloped virus to support an emerging viral pathogen claim (see the Emerging Viral Pathogens Guidance for examples of qualifying viruses) or a human coronavirus (e.g. SARS-CoV-2, ATCC 229E); AND

   Residual disinfection (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and residual virucidal efficacy data for the hardest to kill virus as described above.

ii. If the currently registered product labeling is approved for broad spectrum or hospital non-residual disinfection and virucidal claims, the following data should be submitted for EPA to consider approving residual virucidal claims:

   Residual disinfection (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and residual virucidal efficacy data for the hardest to kill virus as described above; AND

   Note that as described above section II.A, in order to qualify for expedited review, at least one of the approved non-residual virucidal claims should be for a non-enveloped virus to support an emerging viral pathogen claim (see the Emerging Viral Pathogens Guidance for examples of qualifying viruses) or a human coronavirus (e.g. SARS-CoV-2, ATCC 229E).

iii. If the currently registered product labeling is approved for broad spectrum or hospital non-residual disinfection claims with no virucidal claims, the following data should be submitted for EPA to consider approving residual virucidal claims:

   Non-residual virus data for all viruses for which residual claims for viruses are being requested. In order to qualify for expedited review, at least one of the viruses should be a non-enveloped virus to support an emerging viral pathogen claim (see the Emerging Viral Pathogens Guidance for examples of qualifying viruses) or a human coronavirus (e.g. SARS-CoV-2, ATCC 229E); AND

Residual disinfection (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and residual virucidal efficacy data for the hardest to kill virus as described above.

If your application for amended registration includes any additional changes other than those identified above, EPA may not consider it for expedited review.

To ensure the efficient processing of your PRIA submission, please include the following in a cover letter to EPA:

- A subject line that clearly indicates "Existing Product Submission of Efficacy Data for Residual Disinfectant;"
- A list of the submitted efficacy data;
- The identification of the virus(es) used in the submitted data that support the emerging viral pathogen claim(s), SARS-CoV-2 claim(s) or other human coronavirus claim(s); and
- The identification of all the organism(s) and respective study ID number(s) (MRID/s) for which expedited review is being requested.

The following should also be included with your PRIA submission:

- An up-to-date Certification with Respect to Data Citation Form (Form 8570-34) and Data Matrix (Form 8570-35);
- CSF(s) (Form 8570-4);
- An 8570-1 application form;
- A revised master label, both a highlighted version and a clean version, with the updated directions for use for residual disinfection, contact time, and emergent pathogen claims if applicable; and
- If a request to add an emerging viral pathogen claim is being made, please refer to the instructions for adding these claims.
- A PRIA fee payment, in the amount of $4,023, or small business fee waiver request with the appropriate fee for a PRIA A570 action.

Submit your application via the CDX portal. Once you submit or if you have already submitted your application, please email disinfectantslist@epa.gov with your CDX tracking number (CDX_2020_XXXXXXX) with the subject line "Existing Product Submission of Efficacy Data for Residual Disinfectant" so that your submission can be eligible to be expedited.

For questions about what is needed as part of your submission, please contact the Product Manager for your product.

B. Supplemental Residual Antimicrobial Products (e.g. coatings, paints, solid/fixed surfaces)

Submission of new efficacy data to add supplemental residual antimicrobial claims to an already EPA-registered product can be submitted as a PRIA A570 action for expected expedited review. EPA will make every effort to complete the review and make a regulatory decision one to two months faster than the standard four-month timeframe under PRIA. EPA will consider expedited review of applications for amended registration to add

supplemental residual antimicrobial claims for use under either of the following circumstances:

i. For a currently registered product with no approved public health claims, please submit supplemental residual efficacy data relevant to the type of product (e.g., coating vs solid surface) as described in section III.A or III.C above against base bacteria (*Staphylococcus aureus* and *Pseudomonas aeruginosa*) and viruses. In order to qualify for expedited review, at least one of the viruses should be a non-enveloped virus (see the Emerging Viral Pathogens Guidance for examples of qualifying viruses) or a human coronavirus (e.g., SARS-CoV-2, ATCC 229E);
ii. For a currently registered product with bacterial public health claims, please submit supplemental residual efficacy data relevant to the type of product (e.g. coating vs solid surface) as described in section III.A or III.C above against viruses. In order to qualify for expedited review, at least one of the viruses should be a non-enveloped virus (see the Emerging Viral Pathogens Guidance for examples of qualifying viruses) or a human coronavirus (e.g., SARS-CoV-2, ATCC 229E).

To ensure the efficient processing of your PRIA submission, please include the following in a cover letter to EPA:

- A subject line that clearly indicates "Existing Product Submission of Efficacy Data for Supplemental Residual Antimicrobial Product;"
- A list of the submitted efficacy data;
- The identification of the virus claims claim(s) from the submitted data which may include non-enveloped virus(es), SARS-CoV-2 (s) or other human coronavirus(es); and
- The identification of the organism(s) and study ID number(s) (MRID/s) for which expedited review is being requested.

The following should also be included with your PRIA submission:

- An up-to-date Certification w/ Respect to Data Citation Form (Form 8570-34) and Data Matrix (Form 8570-35);
- CSF(s) (Form 8570-4);
- An 8570-1 application form;
- A revised master label, both a highlighted version and a clean version, with the updated directions for use; and
- A PRIA fee payment, in the amount of $4,023, or small business fee waiver request with the appropriate fee for a PRIA A570 action.

Submit your application via the CDX portal. Once you submit or if you have already submitted your application, please email disinfectantslist@epa.gov with your CDX tracking number (CDX_2020_XXXXXXX) with the subject line "Existing Product Submission of Efficacy Data for Supplemental Residual Antimicrobial Coating/Surface Product" so that your submission can be eligible to be expedited.

For questions about what is needed as part of your submission, please contact the Product Manager for your product.

2. Requests for A New Product That Requires the Review of Data Under PRIA:

A. New Product Formulated with A Registered Source of Active Ingredient(s)

For an application for registration of a new pesticide product for residual disinfectant or supplemental residual antimicrobial product intended to be formulated from a registered technical or manufacturing use product, follow the instructions in EPA's previously announced expedited review of certain PRIA submissions for products intended for use against the SARS-CoV-2, the novel human coronavirus that causes COVID-19. Specifically, follow the directions for "Submission of an application for a new pesticide product that requires EPA to review newly submitted efficacy data to support virucidal claims where the product is formulated with a registered source of active ingredient(s)" and include the additional information specified above in Section II (residual disinfectants) or Section III (supplemental residual antimicrobial product) as appropriate. As specified in the expedited PRIA guidance, this is a PRIA A540 action, and the submission should include a PRIA fee payment in the amount of $5,363, or small business fee waiver request with appropriate fee for a PRIA A540 action.

Submit your application via the CDX portal. Once you submit or if you have already submitted your application, please email disinfectantslist@epa.gov with your CDX tracking number (CDX_2020_XXXXXXX) with the either the subject line "New Residual Disinfectant Product- Registered Source" or "New Supplemental Residual Antimicrobial Coating/Surface Product- Registered Source" as appropriate so that your submission can be eligible to be expedited.

B. New Product Formulated with An Unregistered Source of Active Ingredient(s)

For an application for registration of a new pesticide product for residual disinfectant or supplemental residual antimicrobial product intended to be formulated from an unregistered technical or manufacturing use product, follow the instructions in EPA's previously announced expedited review of certain PRIA submissions for products intended for use against the SARS-CoV-2, the novel human coronavirus that causes COVID-19. Specifically, follow the directions for "Submission of an application for a new pesticide product that requires EPA to review newly submitted efficacy data to support virucidal claims where the product is formulated with an unregistered source of active ingredient(s)" and include the additional information specified above in Section II (residual disinfectants) or Section III (supplemental residual antimicrobial) as appropriate. As specified in the expedited PRIA guidance, this may be either a PRIA A540 action or a PRIA A572 action. The submission should include a PRIA fee payment in the amount of $5,363, or small business fee waiver request with appropriate fee for a PRIA A540 action or $13,888 for an A572 action, or small business fee waiver request with the appropriate fee for a PRIA A572 action.

Submit your application via the CDX portal. Once you submit or if you have already submitted your application, please email disinfectantslist@epa.gov with your CDX tracking number (CDX_2020_XXXXXXX) with the subject line "New Residual Disinfectant Product- Unregistered Source" or "New Supplemental Residual Antimicrobial Coating/Surface Product Unregistered Source" so that your submission can be eligible to be expedited.