TABLE 9. ANTIMICROBIALS DIVISION (AD) - NEW PRODUCTS AND AMENDMENTS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
A530	90	New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite all data citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of	An application for registration of an end-use or a manufacturing use pesticide product that is substantially similar, identical in its uses and formulation or that differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment to products that are currently registered. The applicant must identify the similar products for all active ingredients in the proposed product. All applications require the following: • A data matrix is required with the application if it is not a 100% re-packaged product. • Product chemistry data (Group A and B) unless the product is identical (e.g. 100% repackaged product). • The active ingredient listed on the CSF must be an EPA registered product. • In all cases, the registrant must identify the registered similar product for this category. • Acute toxicity requirements must be addressed by using: 1. the cite-all method 2. selective data citation where the applicant owns all required data, or 3. applicant submits specific authorization letter from the data owner. • If a product is using the selective cite or a cite all, the product that is being cited as substantially similar or identical must be clearly identified on the 8570-1	4	$1,833

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		registered end-use or manufacturing use product that requires no data submission nor data matrix. (2) (3)	application form. If multiple products are cited, they must be clearly delineated in the cover letter. The application is not in this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. If the use pattern on the TGAI differs from the proposed products, then additional data are required and the application does not fall within this category. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use, and thus outside of this PRIA category. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. **Substantially similar:** Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the product bears the same use patterns or fewer. Adding to or changing existing use patterns excludes the product from treatment as a substantially similar product. Substantially similar use patterns for public health products are limited to identical organisms on both products. For non-public health products substantially similar use		

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			patterns are limited to identical organisms on both products. Deleting use patterns is acceptable. **Identical products:** Same composition and use patterns as an already registered end-use product. **Manufacturing Use Product:** A 100% re-package of a manufacturing use product that requires no data submission nor data matrix is covered by this category. **Unregistered:** The Agency has not issued an EPA Registration Number (license) for the source material. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that		

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			incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A531	91	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization	An application for registration of an end-use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. All applications require the following: • A data matrix is required with the application. • Product chemistry data (Group A and B) unless the product is identical. In some cases product chemistry data can be satisfied as outlined in PR Notice 98-1. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • The source of the active ingredient must be currently registered (licensed) with the Agency. • In all cases, the applicant must identify the currently registered similar product for this category. The similar product must be identified on the 8570-1 application form. • Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirement must be addressed	4	$2,616

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		letter from data owner. (2) (3)	by using: 1) the cite-all method, or 2) selective data citation where the applicant does not own all required data and does not have a specific authorization letter from the data owner. If a review of data other than product chemistry is needed, the application does not fall into this category. The application does not fall into this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. **Substantially similar:** Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the product bears the same use patterns or fewer. Adding to or changing existing use patterns excludes the product from treatment as a substantially similar product. Substantially similar use patterns for public health products are limited to identical organisms on both products. For non-public health products substantially similar use patterns are limited to identical organisms on both products. Deleting use patterns is acceptable. **Identical products:** Same composition and use patterns as an already registered end-use product.		

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			Manufacturing Use Product: A 100% re-package of a manufacturing use product that requires no data submission nor data matrix is covered by this category. **Unregistered:** The Agency has not issued an EPA Registration Number (license) for the source material. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to		

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			reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A532	92	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2) (3)	An application for registration of an end-use pesticide or manufacturing use product that uses an unregistered source of the active ingredient and that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. All applications require the following: • Product chemistry data (Group A and B) on the end-use product as well as the unregistered source of active ingredient. • The cite-all method must be used to satisfy the generic data requirements. • Acute toxicity requirements must be addressed by using the cite-all method. • In all cases, the applicant must identify the currently registered similar product for this category. The similar product must be identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • A data matrix form is required with the application. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its	5	$7,322

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			own registration service fee. The application is not this category if efficacy, acute toxicity, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data (e.g. acute toxicity, efficacy or product chemistry). An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. If the use pattern on the TGAI differs from the proposed product, then additional data are required and the application does not fall within this category. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. **Substantially similar:** Product must have the same active ingredient, in substantially the same proportion, same chemical composition (solid, liquid, granular), and substantially similar inert ingredients as the already registered product. In addition, substantially similar means that the product bears the same use patterns or fewer. Adding to or changing existing use patterns excludes the product from treatment as a substantially similar product. Substantially similar use patterns for public health products are limited to identical organisms on both products. For non-public health products substantially similar use		

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			patterns are limited to identical organisms on both products. Deleting use patterns is acceptable. **Identical products:** Same composition and use patterns as an already registered end-use product. **Manufacturing Use Product:** A 100% re-package of a manufacturing use product that requires no data submission nor data matrix is covered by this category. **Unregistered:** The Agency has not issued an EPA Registration Number (license) for the source material. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At the time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label		

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			changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A550	93	New end-use product; uses other than FIFRA §2(mm); non-FQPA product (2) (3) (5)	An application for registration of a pesticide product that is not substantially similar or identical in its uses or formulation to products that are currently registered. These applications require product chemistry data (Group A and Group B), acute toxicity data (addressing all 6 endpoints), and possibly leaching data. This category covers an application for a product where a claim of pesticidal activity other than or in addition to contamination, fouling or deterioration caused by bacteria, viruses, fungi, protozoa, algae or slime is made. Refer to FIFRA Section 2(mm) for additional information. Examples would include: • Wood preservatives (e.g., termite claim) • Antifoulants • Ballast water • Any of the above use patterns that would result in a significant increase in the level of exposure (increase in dosage rate, or a change in the route of exposure (fog vs. spray), to the active ingredient of man or other organisms. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable	9	$18,958

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			uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. The applicant must identify the substantially similar product if option to use cite-all or the selective method to support acute toxicity data requirements. If a product is using the selective cite or a cite all, the product that is being cited as substantially similar or identical must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. For generic data only: Either Formulator's Exemption or the cite-all method must be used to satisfy the generic data requirements, or a selective citation where the applicant owns all data. Applicants are encouraged to discuss any requirements for leaching data with the Agency prior to submission of an application. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to		

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			grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A560	94	New manufacturing use product; registered active ingredient; selective data citation (2) (3)	An application for registration of a manufacturing use pesticide (MUP) product that is substantially similar or identical in its formulation to products that are currently registered. An MUP is any product intended (labeled) for formulation into an end use formulated pesticide product. MUPs are only for the formulation into other pesticide products. If the product has other use directions it may not be an MUP. A materials preservative product is not an MUP, rather an end use product as it is contains direction on how to incorporate the product into the material being preserved. All applications require the following: • A data matrix is required with the application. • Product chemistry data (Group A and B) are required. In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted	6	$18,054

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			within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product that is being cited as substantially similar or identical must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. With respect to an application for registration of a new product that is a salt of an already registered active ingredient, where there are not any currently registered products for this salt, the Agency will decide on a case-by-case basis whether an ingredient should be classified as a new active ingredient. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. A different use pattern will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date, then the Agency will issue to the applicant its regulatory decision with the		

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			specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
A565	95	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review (2) (3)	An application for registration of a manufacturing use pesticide product that is not substantially similar or identical in its formulation to products that are currently registered. The proposed product contains an active ingredient that is currently registered. The source of the active ingredient is not registered. An MUP is any product intended (labeled) for formulation into an end use formulated pesticide product. MUPs are only for the formulation into other pesticide products. A materials preservative product is not an MUP, rather an end use product as it is contains direction on how to incorporate the product into the material being preserved. To fit this category all applications require the following: • A data matrix is required with the application. • Product chemistry data (Group A and B) and CSF. • Acute toxicity data must be addressed by submitting data or using: selective data citation. A rationale for a waiver or bridging of these data falls within this category. • The source of the active ingredient is unregistered • The proposed uses must already be on currently registered products.	18	$26,135

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			• The applicant must cite a product with the proposed uses. • The application contains generic data such as toxicity, environmental fate and/or eco-toxicity. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new manufacturing-use product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		

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A572	96	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to REI, or PPE, or use rate) (2) (3) (4) (7)	An application for registration of a pesticide product that is not substantially similar or identical in its uses or formulation to products that are currently registered OR a modification to an existing registration that is not substantially similar or identical in its uses to a currently registered product; that requires risk analysis by the Science Branches (i.e., the Risk Assessment Branch (RAB)) to support the change. Examples of actions in this category include: • Label changes to Directions for Use (including REI, PPE, PHI, application rate, application frequency, application timing, increase in rate, different method of application (fogging vs. spraying); • Exposure change, etc. that require risk analysis by EPA. In some cases, the applicant might not submit new data to support the label amendment, but the Agency would need a determination of whether the existing database would support a change or modification to the amended label; • An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient; and • Review of a unique selective cite generic data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its	9	$18,958

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			own registration service fee. If the Agency determines that endangered species analysis is required according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended to conduct the endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. This extension is contingent on Agency issuing the ESA guidance applicable to this PRIA category. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested new product/amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due date, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label		

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			that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		
A460	97	New end-use product; FIFRA §2(mm) uses only; 0 to 10 public health organisms. (2) (3) (5) (6)	An application for new product registration which requires review of product-specific data. This includes product chemistry, acute toxicology and/or efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an	5	7,322

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			efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula. All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s).		

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			• Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 0-10 public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example:		

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			• If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service		

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			fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		
A461	98	New end-use product; FIFRA §2(mm) uses only; 11 to 20 public health organisms. (2) (3) (5) (6)	An application for new product registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging	6	10,158

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula. All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s). • Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 11-20 public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			(d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		
A462	99	New end-use product; FIFRA §2(mm) uses only; 21 to 30 public health organisms. (2) (3) (5) (6)	An application for new product registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula.	7	12,995

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s). • Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 21-30 public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
A463	100	New end-use product; FIFRA §2(mm) uses only; 31 to 40 public health organisms. (2) (3) (5) (6)	An application for new product registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula. All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted	9	15,831

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s). • Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 31-40		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		
A464	101	New end-use product; FIFRA §2(mm) uses only; 41 to 50 public health organisms. (2) (3) (5) (6)	An application for new product registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an	10	18,668

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula. All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s).		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			• Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 41-50 public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example:		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			• If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			(b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		
A465	102	New end-use product; FIFRA §2(mm) uses only; 51 or more public health organisms. (2) (3) (5) (6)	An application for new product registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption.	11	21,505

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			• Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula. All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s). • Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 51 or more public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		
A470	103	Label amendment requiring data review; 0 to 10 public health organisms. (3) (4) (5) (6)	An application for amended registration which requires review of product-specific data. This includes product chemistry, acute toxicology and/or efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula.	4	5,493

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s). • Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 0-10 public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
A471	104	Label amendment requiring data review; 11 to 20 public health organisms. (3) (4) (5) (6)	An application for amended registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula. All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted	5	8,506

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s). • Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 11-20		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		
A472	105	Label amendment requiring data review; 21 to 30 public health organisms. (3) (4) (5) (6)	An application for amended registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an	6	10,219

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula. All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s).		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			• Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 21-30 public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example:		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			• If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			(b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		
A473	106	Label amendment requiring data review; 31 to 40 public health organisms. (3) (4) (5) (6)	An application for amended registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption.	7	11,933

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			• Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula. All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s). • Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 31-40 public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		
A474	107	Label amendment requiring data review; 41 to 50 public health organisms. (3) (4) (5) (6)	An application for amended registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula.	8	13,646

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s). • Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may request 41-50 public health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
A475	108	Label amendment requiring data review; 51 or more public health organisms. (3) (4) (5) (6)	An application for amended registration which requires review of product-specific data. This includes product chemistry, acute toxicology and efficacy data. The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word and/or precautionary language changes requiring data review/review of acute toxicity data. • Changes to active ingredient (a.i.) sources - change from one unregistered source to another or change from a registered source to an unregistered source. • Any submission requesting a Child Resistant Packaging exemption. • Any formula change that requires product specific data including toxicity, product chemistry, and efficacy data (including confirmatory data). Routine formula changes are not PRIA actions. Routine formula changes are those which do not require data to support the change such as a surfactant, dye or other addition or modification to the inert ingredients in the formula. All applications require the following: • A data matrix. • All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition	9	15,766

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. • If a product is using the selective cite or a cite all, the product supporting the data requirements must be clearly identified on the 8570-1 application form. If multiple products are cited, they must be clearly delineated in the cover letter. • The currently approved Basic CSF and any proposed CSF(s). • Cover letter, clearly outlining the proposed action by the registrant and any other supportive documentation necessary for EPA to conduct the review. • Proposed label. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of application will result in the application being treated as a new use. The company is required to provide a cited label to support the proposed uses by showing that the use pattern and rates do not exceed currently registered products. Excludes: product-specific data required as a term of registration, such as storage stability and corrosion characteristics data. NOTE: Any significant increase in exposure requiring science review/a risk assessment (increase in dosage rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Under this PRIA category, a single application may 51 or more public		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			health organisms for review. The number of supporting data volumes per organism does not impact the total organism count, unless the same organism is used to satisfy various guidelines. Each organism tested with a specific guideline is counted once, this may indicate that one organism is counted multiple times if it is applied to multiple guidelines. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism. • If one organism is tested for three different efficacy guidelines/study methods, each guideline would count as one organism. For example, if Staphylococcus aureus is tested to verify efficacy under non-food contact sanitizers, food contact sanitizers and disinfectants guidelines, it would count as three separate organisms. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested label amendment registration. If the label issues cannot be resolved prior to the PRIA decision review time due the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. At that time the applicant must either (a) agree to all of the label changes and submit a revised label that incorporates all of these label changes; or (b) does not agree with one or more of the label changes and request up to 30 days to		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			reach agreement with the Agency and submit a revised label that incorporates all of the agreed upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice. Registration amendment fees: (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant- initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast- track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fee		

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(5) The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements.

(6) Once an application for an amendment or a new product with public health organisms has been submitted and classified into any of categories A460 through A465 or A470 through A475, additional organisms submitted for the same product before the first application is granted will result in combination and reclassification of both the original and subsequent submissions into the appropriate new category based on the sum of the number of organisms in both submissions. Submission of additional organisms would result in a new PRIA start date and may require additional fees to meet the fee of a new category.

(7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.