PRIA 4 Interpretations

TABLE 9. ANTIMICROBIALS DIVISION - NEW PRODUCTS AND AMENDMENTS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
A530	81	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. data owner. Category also	An application for registration of an end-use or a manufacturing use 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 product or products for all active ingredients in the proposed product. All applications require the following: • A data matrix is required with the application unless it is identical to currently registered product (e.g. a 100% repackaged product). • Product chemistry data (Group A and B) unless the product is identical to a currently registered product (e.g. 100% repackaged product). • The source of the active ingredient must be currently registered (licensed) with the Agency. • In all cases, the registrant must identify the registered similar product(s). • 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. The application is not in 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 products, then additional data are required and the application does not fall within this category. If the product contains an unregistered active ingredient source, it does not belong in this category. **Substantially similar:** Product must have the same active ingredient, in substantially the	4	1,342

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		includes 100% re-package of registered end-use or manufacturing use product that requires no data submission nor data matrix. (2) (3)	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 required for both products. Deleting use patterns is acceptable. **Identical products:** Same composition and use patterns as an already registered end-use product or manufacturing use product. **Manufacturing Use Product:** A product intended (labeled) for formulation or repackaging into an end use formulated product. 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 and if a PRIA due date time extension has not been agreed upon, 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		

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			without prejudice.		
A531	82	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 the applicant does not own all required data and does not have a specific authorization letter from data owner. (2) (3)	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 formulation to a currently registered product. In some cases, product chemistry data can be satisfied as outlined in PR Notice 98-1. • All inert ingredients must be already approved for the applicable uses in the product. • 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(s). • Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirement must be addressed 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, and/or child resistant packaging data are submitted and must be reviewed to support the application. An application proposed as a 100% repackaged product does not fall within this category (see category A530). 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.	4	1,916

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			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. For the definition of a Substantially similar and Identical, please see category A530. 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 and if a PRIA due date time extension has not been agreed upon, 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.		
A532	83	New product; identical or substantially similar in composition and use to a registered	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.	5	5,363

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
		product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2) (3)	• 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(s) • A data matrix form is required with the application. 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. For the definition of a Substantially similar and Identical, please see category A530. 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 and if a PRIA due date time extension has not been agreed upon, 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.		
A540	84	New end use	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.	5	5,363

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		product; FIFRA § 2(mm) uses only; up to 25 public health organisms (2) (3)(5)(6)	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 inerts must be already approved or pending with the Agency for the applicable uses in the product. • Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting the required data. A rationale for a waiver of these data falls within this category. • 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. • For a wood preservative, antifoulant or ballast water treatment product, a claim that differs from those described in FIFRA 2mm will place the product in the A550 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. 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 and if a PRIA due date time extension has not been agreed upon, 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		

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			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. Up to 25 public health organisms may be requested within a single application under this PRIA category. The number of supporting data volumes per organism does not impact the total organism count. One organism is counted irrespective of the total number of organisms that must be tested to support a marketing claim/ testing protocol/data guideline. 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 guideline/protocol/marketing claim requires three organisms to be tested; the requested count for that application will be three public health organisms. Once a submission for a new product with public health organisms has been submitted and classified in either A540 or A541, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number or organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category.		
A541	85 new	New end use product; FIFRA § 2(mm) uses only; 26-50 public health organisms	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. All applications require the following:	7	8,925

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		(2)(3)(5)(6)	• 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 inerts must be already approved or pending with the Agency for the applicable uses in the product. • Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting the required data. A rationale for a waiver of these data falls within this category. • 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. • For a wood preservative, antifoulant or ballast water treatment product, a claim that differs from those described in FIFRA 2mm will place the product in the A550 category. A different pattern of use that significantly changes or increases exposure such as a rate increase or different method of application will result in the application being treated as a new use. 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 and if a PRIA due date time extension has not been agreed upon, 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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			Between 26 and 50 public health organisms must be requested within a single application under this PRIA category. The number of supporting data volumes per organism does not impact the total organism count. One organism is counted irrespective of the total number of organisms that must be tested to support a marketing claim/ testing protocol/data guideline. 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 guideline/protocol/marketing claim requires three organisms to be tested; the requested count for that application will be three public health organisms. [6]Once a submission for a new product with public health organisms has been submitted and classified in either A540 or A541, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number or organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category.		
A542	86 new	New end use product; FIFRA § 2(mm) uses only; ≥ 51 public health organisms (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. 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 inerts must be already approved or pending with the Agency for the applicable uses in the product. • Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirements must be addressed by using: 1) the cite-all method, or 2) selective data citation which includes submitting the required data. A rationale for a waiver of these data falls within this category.	10	15,750

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			• 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. • For a wood preservative, antifoulant or ballast water treatment product, a claim that differs from those described in FIFRA 2mm will place the product in the A550 category. A different pattern of use that significantly changes or increases exposure such as a rate increase or different method of application will result in the application being treated as a new use. 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 and if a PRIA due date time extension has not been agreed upon, 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. A minimum of 51 public health organisms must be requested within a single application under this PRIA category. The number of supporting data volumes per organism does not impact the total organism count. One organism is counted irrespective of the total number of organisms that must be tested to support a marketing claim/ testing protocol/data guideline. For example: • If data is submitted in two volumes for one organism; the requested count for that application will be one public health organism.		

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			• If one guideline/protocol/marketing claim requires three organisms to be tested; the requested count for that application will be three public health organisms. Once a submission for a new product with public health organisms has been submitted and classified in either A540 or A541, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number or organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category.		
A550	87	New end use product, uses other than FIFRA sec. 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 endpoints), and possibly leaching data. This type of application would be 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.	9	13,888

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			All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. 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 grant the requested new product registration. If the label issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, 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	88	New manufacturing use product; registered active ingredient; selective data citation (2)(3)	An application for registration of a manufacturing use pesticide product that is substantially similar or identical in its formulation to products that are currently registered. New Manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. This product does not contain directions for use of the product as distributed or sold, or after combination by the user with other substances. 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	6	13,226

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			chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • All inert ingredients must be approved for the applicable uses in the product. An application proposed as a 100% re-packaged product does not fall within this category. 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 manufacturing 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 and if a PRIA due date time extension has not been agreed upon, 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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A565	89 new	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. New manufacturing use product is any product intended (labeled) for formulation or repackaging into an end use formulated pesticide product. This category may also include an end-use product relying on a new generic data package. 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. • The applicant must cite a product with the proposed uses. • The application contains generic data such as toxicity, environmental fate and/or eco-toxicity. 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 and if a PRIA due date time extension has not been agreed upon, 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)	12	19,146

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			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.		
A570	90	Label Amendment requiring data review; up to 25 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. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word changes/review of acute toxicity data • Changes to active ingredient (ai) sources - change from one unregistered source to another or change from a registered source to an unregistered source • Any submission requesting a CRP 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. • A data matrix is required with the application. Excludes: product-specific data required as a term of registration, such as storage stability 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. Up to 25 public health organisms may be requested within a single application under this PRIA category. The number of supporting data volumes per organism does not impact the total organism count. One organism is counted irrespective of the total number of organisms that	4	4,023

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			must be tested to support a marketing claim/ testing protocol/data guideline. 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 guideline/protocol/marketing claim requires three organisms to be tested; the requested count for that application will be three public health 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 date and if a PRIA due date time extension has not been agreed upon, 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. (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		

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			fees. (e) Submissions with data and requiring data review are subject to registration service fees.		
A573	91 new	Label amendment requiring data review; 26-50 public health organisms (2)(3)(5)(7)	An application to amend an existing registration which requires review of product-specific data. This include product chemistry, acute toxicology, and efficacy data. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word changes/review of acute toxicity data • Changes to active ingredient sources - change from one unregistered source to another or change from a registered source to an unregistered source • Any submission requesting a CRP exemption • Any formula change that requires product specific data including toxicity, product chemistry, 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. • A data matrix is required with the application. Excludes: Product-specific data required as a term of registration, such as storage stability data. **NOTE:** Any significant increase in exposure requiring science review/a risk assessment (increase in rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. Between 26 and 50 public health organisms must be requested within a single application under this PRIA category. The number of supporting data volumes per organism does not impact the total organism count. One organism is counted irrespective of the total number of organisms that must be tested to support a marketing claim/ testing protocol/data guideline. For example:	6	6,668

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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 guideline/protocol/marketing claim requires three organisms to be tested; the requested count for that application will be three public health 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 date and if a PRIA due date time extension has not been agreed upon, 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. 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 fees. Once a submission for a label amendment with public health organisms has been		

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			submitted and classified in either A570 or A573, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number or organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category.		
A574	92 new	Label amendment requiring data review; ≥ 51 public health organisms (2)(3)(5)(7)	An application to amend an existing registration which requires review of product-specific data. This include product chemistry, acute toxicology, and efficacy data. Examples include: • Any submission that includes efficacy data or that requires an efficacy review. • Signal word changes/review of acute toxicity data • Changes to active ingredient sources - change from one unregistered source to another or change from a registered source to an unregistered source • Any submission requesting a CRP exemption • Any formula change that requires product specific data including toxicity, product chemistry, 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. • A data matrix is required with the application. Excludes: Product-specific data required as a term of registration, such as storage stability data. **NOTE:** Any significant increase in exposure requiring science review/a risk assessment (increase in rate, different method of application (fogging vs. spraying) will be treated under category A572, or as a new use. A minimum of 51 public health organisms must be requested within a single application under	9	11,550

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			this PRIA category. The number of supporting data volumes per organism does not impact the total organism count. One organism is counted irrespective of the total number of organisms that must be tested to support a marketing claim/ testing protocol/data guideline. 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 guideline/protocol/marketing claim requires three organisms to be tested; the requested count for that application will be three public health 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 date and if a PRIA due date time extension has not been agreed upon, 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. (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		

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			subject to registration service fees.		
A572	93	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)	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. by the Risk Assessment and Science Support Branch (RASSB), Product Science Branch (PSB), etc.) 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. EPA-initiated amendment shall not be charged fees. 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 of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. 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	9	13,888

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			issues cannot be resolved prior to the PRIA decision review time due date and if a PRIA due date time extension has not been agreed upon, 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. (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 fees.		