TABLE 5. REGISTRATION DIVISION (RD) - AMENDMENTS TO REGISTRATION

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
R340	68	Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/ modifying pest(s) claims for up to 2 target pests; excludes products requiring or citing an animal safety study (2)(3)	An application that proposes modification in the label, formula, or packaging of a registered product which requires the submission of data or the citation of data by the registrant that requires an analysis by the Registration Division (RD) only. For the purposes of public health claims, this category includes adding/modifying pest(s) claims for up to 2 target pests. This category excludes animal products submitting or citing animal safety data for support of the amendment application. To fit this category the inert ingredients used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood). Examples of actions in this category include alternate formulations with product chemistry data, label changes to precautionary statements based on product chemistry and/or acute product toxicity data, efficacy data (up to 2 target pests), or child resistant packaging data. An amendment requesting the addition of an unregistered source of active ingredient does not belong in this category, and instead falls under the R351 category. Registered source of active ingredient means that the active ingredient source product has been issued an EPA Registration Number (license). EPA-initiated amendments shall not be charged registration service fees. If more than 2 target pests are submitted, then the action belongs in R341. For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014).	4	7,508

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			To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. <u>Total Number of PRE Example:</u> A registrant wishes to amend their label by adding pest claims for 2 target pests requiring efficacy for a currently registered product. The application will not require any animal safety data. The application will include submitted or cited product performance data to support claims against pests of public health significance. The proposed amendment example may include a general cockroach claim, a claim to control Oriental cockroaches and a general tick claim. In this example, the data necessary to support the desired claims are not on file at the Agency, so the registrant must submit or cite data with their application. To support the general cockroach claim, the Agency requires testing on both American and German cockroaches, so the prospective registrant must develop and submit or cite data supporting the desired claim on both species. Cockroaches are the general pest group and American and German cockroaches are the representative test species for the group; therefore, the studies supporting "cockroaches" count as 1 PRE for purposes of determining the PRIA category. Oriental cockroaches are not part of the general cockroaches pest group, they are a specific pest species. However, all studies supporting cockroach claims, including oriental cockroaches, count as 1 PRE, because there is already a general pest claim for cockroaches. If the registrant wishes to support a claim against "ticks", another pest group, they must submit studies for each lone star ticks, deer (blacklegged) ticks, and American or brown dog ticks to support the general tick claim. The data to support the three required species of ticks count as 1 PRE for purposes of determining the PRIA category. Thus, data were submitted or cited to support claims against 2 pests requiring efficacy (i.e., cockroach (pest group), including Oriental cockroach specific claim; and tick (pest group)). If the registrant wishes to add a claim against the "gulf coast tick, which may transmit *Rickettsia parkeri*" an additional study will be required. Gulf coast ticks are not part of the		

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			general tick pest group, and not only is additional data required for this pest, but they also count as an additional PRE. This pest is one of the exceptions that is not covered by a general pest group or sub-group claim. The application would then contain product performance data supporting 3 pests requiring efficacy (i.e., cockroach (pest group), including Oriental cockroach specific claim; tick (pest group); and gulf coast tick, which may transmit *Rickettsia parkeri*). 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 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.		
R341	69	Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests; excludes products requiring or citing an	An application that proposes modification in the label, formula, or packaging of a registered product which is substantially similar or is not substantially similar to a currently registered product and which requires the submission of data or the citation of data by the registrant which requires an analysis by the Registration Division (RD) only. For the purposes of public health claims, this category includes adding/modifying pest(s) claims for greater than 2 target pests. This category excludes on-animal products submitting or citing animal safety data for support of the amendment application. To fit this category the inert ingredients used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood). Examples of actions in this category include alternate formulations with product chemistry data, label changes to precautionary statements based on product chemistry and/or acute product toxicity data, efficacy data (greater than 2 target pests), and child resistant packaging data. An amendment requesting the addition of an unregistered source of active ingredient does not belong in this category, and instead falls under the R351 category. Registered source of	6	9,014

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		animal safety study (2)(3)	active ingredient means that the active ingredient source product has been issued an EPA Registration Number (license). EPA-initiated amendments shall not be charged registration service fees. If 2 or less target pests are submitted, then the action belongs in R340. For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. Refer to the interpretation in R340 for examples on how to calculate the total number of PRE. 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 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		

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			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.		
R345	70	Amending on-animal products previously registered, with the submission of data and/or waivers for only: 1. animal safety and 2. pest(s) requiring efficacy and/or 3. product chemistry and/or 4. acute toxicity and/or 5. child resistant packaging (2)(3)(4)	This category applies to an application that proposes modifying an existing, registered label for an end use pesticide animal product by adding additional claims against pest(s) requiring efficacy for use on adults or juveniles or breeding animals of the same species. For example, spot-on products are generally labeled animal specific, in that a product is labeled for dogs or cats, but not generally both, while shampoos and sprays may be labeled for both animals (dogs and cats). To fit this category, this amendment would require the following but are not limited to: • A data matrix and data compensation forms are required with the application. • All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood). In those cases where the product relies upon a pending inert clearance, the new animal safety studies must be conducted with the pending inert in the tested product as it is intended to be marketed and sold as the end use product. • If new efficacy claims are sought, then new pest efficacy data matching the claim(s) are required. • If the packing type has changed (e.g., spot-on vs. stripe-on) so that the dose volume is altered (new or different), new child resistant packaging data is required. • Which companion animal safety studies are required is based upon the specific label claims in the proposed label. For example, if the proposed end use product label claim is to use the product on 12-week-old kittens weighing =3 lbs and on breeding cats, then two companion animal studies are required: the first using kittens = 12 weeks of age and weighing at least 3 lbs. and a second study on pregnant and nursing adult cats. Each of these studies must demonstrate an adequate margin of safety. EPA-initiated amendments shall not be charged registration service fees.	7	13,276

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			For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" (hereafter referred to as PRE) are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, 40 CFR (Code of Federal Regulations) part 158, subpart R (87 FR 22464, https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-R). This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in PRN 2023-1 (https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0014). To determine the number of PREs, which determines the appropriate PRIA category, pest groups, sub-groups and pest-specific claims as listed in 40 CFR Part 158, subpart R should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, flies, etc.), each group will count as 1 PRE. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, large biting flies, subterranean termites, fire and harvester ants, fire ants, etc.), or specific species (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest count as 1 PRE. In addition, one individual PRE may encompass multiple claims. For example, if a registrant seeks both a general efficacy claim *and* a speed-of-kill claim against the singular PRE Group "Cockroaches", then this will count as a *singular* PRE as long as the submitted or cited data adequately addresses each claim against the PRE. 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 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.		

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R350	71	Amendment requiring data review in science divisions (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or Preharvest Interval, or use rate, or number of applications; or add aerial application; or modify Ground Water/Surface Water advisory statement (2)(3)(5)	An application that proposes modification to the label of a registered product that is not substantially similar to a currently registered product and that requires risk analysis by the Agency (i.e., by the Health Effects Division (HED), the Environmental Fate and Effects Division (EFED), the Biological and Economic Analysis Division (BEAD), 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, addition of aerial or chemigation application methods consistent with PR Notice 87-1 and 93-2, ground water or surface water advisory statements, 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 amendments shall not be charged registration service fees. 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 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. 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.	9	19,906
R351	72	Amendment adding a new unregistered source of active ingredient (2)(3)	An application that proposes the addition of a new unregistered source of active ingredient to a registered product. A multiplier applies for each individual manufacturing site/new unregistered source being added under one package. If the submission includes addition of multiple unregistered sources/production sites, Group A data for each unregistered source should be submitted in separate MRIDs. Alternatively, separate R351 applications can be submitted for each new manufacturing site/new unregistered source. An example of this	8	19,906

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			category would be adding a new production facility for a registered technical product or adding a source of a.i. to an end use product that is not an EPA-registered source product. To fit this category, all applications require the following: • Certification with respect to Citation of Data and Data Matrix. • All of the inerts used in the product must be either approved, pending with the Agency, or a new inert petition submitted within the package for the applicable uses (food or nonfood). • If amending an MUP, then one set of product specific product chemistry data and CSF is required (under #1 below). • If amending an end-use product, then two sets of product chemistry data are required (under #1 and #2 below). (1) Product chemistry (Group A and B) on the unregistered source of the active ingredient and CSF. The applicant must identify to the Agency the toxicity of the impurities associated with the active ingredient; particularly impurities of toxicological significance (at any level). The impurity profile of the unregistered source of the active ingredient will be compared to registered source. The impurity profile of the unregistered source of the active ingredient either results in new impurities; or impurities of toxicological significance, or if the toxicity of new impurities are unknown to the applicant, then the application is submitted to HED for review. (2) Product chemistry data (Group A and B) for the end use product and CSF. In some cases, product chemistry data can be satisfied as outlined in Pesticide Registration Notice 98-1. • Acute toxicity, public health pest efficacy and/or child resistant packaging data requirements must be addressed by using selective data citation. A rationale for a waiver or bridging of these data falls within this category. However, this code does not include new acute toxicity/efficacy data review. A data matrix must have been previously approved to fit in this category. • Proposed label for the MUP and/or end use product EPA-initiated amendments shall not be charged registration service fees. 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 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		

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			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.		
R352	73	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data (2)(3)	An application that proposes modification in the label of a registered end-use or manufacturing use product, which is substantially similar or identical to a currently registered product and proposes to add uses to the label that already exist on the label of that single substantially similar or identical product identified by the applicant. This category does not require review of new data or bridging of data. Data that are selectively cited to support the amendment must have already been reviewed by the Agency for the same uses, formulation type, active ingredient and claims. This code is not applicable to products that are currently registered as 100% repack of a registered product. Review of product chemistry/acute toxicity/efficacy and/or performance data are not included in this category. To fit into this category, applications require the following: • A completed data matrix is required identifying the selective method of support. • The application/amendment form must cite the substantial similar or identical product where the uses already exist. • If using the cite-all method of support, the amendment application does not fall into this category, and may be considered as a non-PRIA fast-track submission. EPA-initiated amendments shall not be charged registration service fees. 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 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	8	19,906

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			upon label changes, which the Agency has 2 business days to review; or (c) withdraw the application without prejudice.		
R371	74	Amendment to Experimental Use Permit; (does not include extending a permit's time period (3)	An application to amend an Experimental Use Permit (EUP) application for the currently registered uses. The application requires review of the amendment, including data review and/or new risk assessments for the currently registered uses. If new uses are being proposed, then the application would not fall within this category. 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 amendment to the experimental use permit. 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.	6	15,187

(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) (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 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.

(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) For the purposes of classifying proposed registration actions into PRIA categories, ‘‘pest(s) requiring efficacy’’ are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ash borer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, sub-groups, and pest- specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest sub-group (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each sub-group or specific pest will count as 1.

(5) 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.