PRIA 4 Interpretations

TABLE 1. REGISTRATION DIVISION – NEW ACTIVE INGREDIENTS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
R010	1	New Active Ingredient, Food use (2) (3)	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application for a new active ingredient are covered by the base fee for the application in this category if submitted in the same package. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such	24	790,737

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			associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 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 active ingredient 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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R020	2	New Active Ingredient, Food use; reduced risk (2) (3)	An application that proposes a food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. A "reduced risk" (https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as "reduced risk" when compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The	18	658,947

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			fee category will be changed to category R010, and the action will receive the R010 decision review timeframe. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 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 active ingredient registration. If		

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			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.		
R040	3	New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45% of fee toward new	An Experimental Use Permit (EUP) application for food use(s) of an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. The application proposes a food use. The use requires the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. The application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application(s). All uses (food and non-food) included in any original application or petition for a new active ingredient are covered by the base fee for the application in this category if submitted simultaneously. Examples of food uses include: use on foods, for example, corn or apples; aquatic uses involving potable water, irrigation, or requiring tolerances for fish, or shellfish; uses on areas where food may be grown or raised such as pasture, rangeland, home garden, beehive, and uses involving livestock, such as livestock housing, livestock dips, and livestock ear tags. The Agency will not accept a certification for crop destruct once the review clock has	18	485,628

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		active ingredient application that follows (3)	started. A change to a crop destruct application would require the applicant to withdraw their application and start the process application again. 45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP application. 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 4 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 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.		
R060	4	New Active Ingredient, Non- food use; outdoor (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not	21	549,366

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			indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include, for example, treatment of ornamentals in a shade house or turf uses. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 weeks		

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			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 active ingredient 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.		
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include, for example, treatment of ornamentals in a shade house or turf uses. A "reduced risk" (https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as "reduced risk" when	16	457,805

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			compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the category R060 and the action will receive R060 decision review timeframe. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical		

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			deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 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 active ingredient 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.		
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for	An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Outdoor use means any use that is not indoor as described in the indoor category. All non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Non-food outdoor uses could include, for example, treatment of ornamentals in a shade house or turf uses. 45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP application.	16	339,875

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		registration; credit 45% of fee toward new active ingredient application that follows (3)	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 4 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 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.		
R110	7	New Active Ingredient, Non- food use; indoor (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not	20	305,544

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			covered in this category. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 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 active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision		

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			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.		
R120	8	New Active Ingredient, Non- food use; indoor reduced risk (2) (3)	An application that proposes a non-food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection and indoor residential treatments (i.e. cockroach treatments). Treatment of ornamentals in a shade house is classified as outdoor uses and is not covered in this category. A "reduced risk" (https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program) submission must accompany the application for registration. The Agency's Reduced Risk Committee will evaluate the submission and make the determination, based on criteria and guidance listed in PR Notice 97-3 and in FIFRA 3(c)(10) (B) (-iv), whether the requested use(s) qualify as "reduced risk" when	14	254,620

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			compared to currently registered pesticides for the same use(s). The reduced risk status of any use of a chemical is an initial assessment. Should information warrant, or should the Agency determine at any time that the data base for the chemical is unacceptable or upon a more thorough review found to be insufficient to demonstrate that the use/application is reduced risk, the Agency may reject reduced risk status. In the event that any uses do not qualify as "reduced risk" by decision of the Reduced Risk Committee, the application will not receive the reduced risk decision timeframes. The fee category will be changed to the category R110 and the action will receive the R110 decision review timeframe. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was		

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			neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 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 active ingredient 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.		
R121	9	New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for	An Experimental Use Permit (EUP) application for non-food use(s) of an active ingredient that is not contained as an active ingredient in any currently U.S. registered pesticide product. A non-food use includes a proposed use that is not a food use as described in the food use categories. Indoor means that the proposed use is for use inside of manmade structures. All indoor non-food uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. Some examples of indoor uses are termiticide structural protection, and indoor residential treatments (i.e. cockroach treatments).	18	191,444

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		registration; credit 45% of fee toward new active ingredient application that follows (3)	Treatment of ornamentals in a shade house is classified as an outdoor use and is not covered in this category. 45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP application. 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 4 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 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 this 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.		
R122	10	Enriched isomer(s) of registered mixed- isomer active	An application that proposes using an enriched isomer of an active ingredient, where such enriched isomer is not currently contained as an active ingredient in any U.S. registered pesticide product. This category consists of active ingredients that are a variation on the molecular structure or composition of a registered product and which will cite at least some of the generic data conducted with a registered product. If a food	18	332,985

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		ingredient (2) (3)	use is included in this new active ingredient package, the use may require the establishment of or the exemption from the requirement of a tolerance under section 408 of the FFDCA. If a tolerance or exemption from the requirement of a tolerance is required, the application submission must contain a petition to establish tolerances or exemption(s) from tolerance for all food/feed commodities covered by the pending registration application. All uses (food and non-food) included in the original application or petition for each new active ingredient are covered by the base fee for the application in this category if submitted in this package. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical		

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			deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 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 active ingredient 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.		
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; residues not expected in raw agricultural	An application for seed treatment only that proposes a use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product that is not expected to result in residues in raw agricultural commodities. All uses included in the original application for each new active ingredient are covered by the base fee for the application in this category if submitted in this package. In order for a food crop seed treatment to be considered in this category, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop. Guidance is available at (https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines). If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered	18	495,455

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		commodities (2) (3)	to be food uses requiring tolerances and fall into a different category. All of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. A maximum of five new products are covered by the base fee. After the first five new products, each application for an additional new product or new inert ingredient approval that is submitted within this new active ingredient package is subject to the registration service fee for a new product or a new inert ingredient approval. All such associated applications that are submitted together will be subject to the new active ingredient decision review time. Until the new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be charged a new active ingredient service fee and decision review timeframe. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency, after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient application. The Agency will provide the applicant with a pre-decisional determination 4 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 active ingredient registration. If the label issues cannot be resolved prior to the PRIA decision review time due date		

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			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.		
R125	12	New Active Ingredient, Seed treatment; Experimental Use Permit application, submitted before application for registration; credit 45% of fee toward new active ingredient application that follows (3)	An Experimental Use Permit (EUP) application for seed treatment only that proposes a use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product that is not expected to result in residues in raw agricultural commodities. All uses included in the original application for a new active ingredient are covered by the base fee for the application in this category. In order for a food crop seed treatment to be considered in this category, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop. Guidance is available at (https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines). If residues occur in the aerial portion of the plant, or if there is no data available to make this determination, seed treatments are considered to be food uses requiring tolerances and fall into a different category. 45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP application. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.	16	339,875

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			The Agency will provide the applicant with a pre-decisional determination 4 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 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.		