TABLE 10. ANTIMICROBIALS DIVISION (AD) - EXPERIMENTAL USE PERMITS AND OTHER ACTIONS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
A520	109	Experimental Use Permit application non-food use (2) (3)	Application for an experimental use permit for an active ingredient already registered (i.e., not a new active ingredient). Allows a registered pesticide to be used for an off-label non-food use, under controlled, field or actual use conditions so that data required to support a FIFRA section 3 registration can be developed (e.g., data necessary to evaluate efficacy and potential for safe use or adverse effects on humans and the environment such as a swimming pool use). An EUP for a new AI does not fall under this category. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date. If the Agency determines that endangered species analysis is required	9	9,151

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			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. 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.		
A521	110	Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study	An application that requires the review of a modified protocol where only minor changes are made to an existing efficacy method (e.g. AOAC International, ASTM, AATCC, EPA guideline 810 or an AD approved method described in A431). The protocol should be submitted before any product registration testing has been done under the modified protocol. A draft label with proposed directions for use and use claims must accompany the protocol and the application. The draft label submitted with this application is not subject to the Agency's approval. Examples of minor changes include (but are not limited to): varied test conditions, modification of standard method to support additional microorganisms [e.g., Germicidal Spray Products test for spore-formers], changes to surface types/carriers, changes in	6	$6,776

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
		protocol; applicant-initiated; Tier 1.	inoculum preparation and inoculation, changes to required test microbes, and changes to support alternate application types [e.g., foams, electrostatic sprayer]. A pre-registration meeting is strongly recommended prior to submission of the protocol. The Agency will make every effort during this meeting to determine if the protocol falls under the Tier 1 category. If, during further review, the Agency determines that a Tier l protocol should be elevated to Tier 2 status (A522), the applicant will receive notification prior to this change.		
A522	111	Review of public health efficacy study protocol conducted outside of AD by members of the AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol; applicant-initiated; Tier 2.	An application that requires the review of a new public health efficacy protocol, or a major change to an existing efficacy method (e.g. AOAC International, ASTM, AATCC, EPA guideline 810, or an AD approved method described in A431). Applies to a study design that requires review by external members of an ad hoc AD Efficacy Protocol Review Expert Panel. A draft label with proposed directions for use and use claims must accompany the protocol and the application, along with proposed performance measures. The draft label submitted with this application will not be reviewed or approved under this category. Examples of major protocol changes would include surrogate consideration, field test component, simulated or in-use testing, changes in growth conditions [e.g., novel protocols for products with label claims that don't meet the current recommended conventional sterilant/disinfectant/sanitizer standards (e.g., treated materials). A pre-registration meeting is recommended prior to submission of the protocol. The Agency will make every effort during this meeting to determine if the protocol is Tier 2	12	$17,424

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
A537	112	New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	An Experimental Use Permit (EUP) application for direct food use(s) of an active ingredient that is not currently registered. The Antimicrobial Pesticide Use Site Index (USI) describes direct food uses and provides guidance to determine if labeled uses require the establishment of a tolerance or exemption from the requirement of a tolerance. The USI gives examples of the general types of use sites that are commonly listed on antimicrobial labels. All direct food uses 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. A credit of 45% of the New Active Ingredient fee will be applied to the application that follows. 45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. If 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	18	219512

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			guidance applicable to this PRIA category.		
A538	113	New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows. (3)	An Experimental Use Permit (EUP) application for a new indirect food use(s) of an active ingredient that is not currently registered. The Antimicrobial Pesticide Use Site Index (USI) describes indirect food uses and provides guidance to determine if labeled uses require the establishment of a tolerance or exemption from the requirement of a tolerance. The USI gives examples of the general types of use sites that are commonly listed on antimicrobial labels. All indirect food uses 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. A credit of 45% of the New Active Ingredient fee will be applied to the application that follows. 45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. If the Agency determines that endangered species analysis is required according to section 33(c)(3)(B) for this specific type of action, the	18	137198

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			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.		
A539	114	New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	An Experimental Use Permit (EUP) application for nonfood use(s) of an active ingredient that is not currently registered. The Antimicrobial Pesticide Use Site Index (USI) describes nonfood uses and provides guidance to determine if labeled uses require the establishment of a tolerance or exemption from the requirement of a tolerance. The USI gives examples of the general types of use sites that are commonly listed on antimicrobial labels. All nonfood uses included in the application are covered by the base fee for the application in this category if submitted simultaneously. A credit of 45% of the New Active Ingredient fee will be applied to the application that follows. A credit of 45% of the New Active Ingredient fee will be applied to the application that follows. 45% of this category's fee will be credited against the new active ingredient's application fee whose submission follows that of this EUP. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee.	15	$132,094

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			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.		
A529	115	Amendment to Experimental Use Permit; requires data review or risk assessment (2) (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. All inert ingredients used in the product must be EPA approved for the proposed use(s), pending approval with the Agency for the applicable uses, or included in an inert petition submitted within the package for the applicable uses. Each application for a new inert approval submitted in this package is subject to its own registration service fee. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested experimental use permit. If the label issues cannot be resolved prior to the PRIA decision review time due date, then the Agency will issue to the applicant its regulatory decision with the specific label changes and supporting documentation on or just before the PRIA decision review time due date.	9	$16,383

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			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. 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.		
A523	116	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols)	An application for approval of each study protocol submitted other than for public health studies. Applicant provides a written copy of the protocol along with any specific questions about the protocol. The fee for this category is multiplied by each additional protocol submitted for review.	9	$17,424
A571	117	Science reassessment: refined ecological risk, and/or endangered	An application in which a request is made to change or refine the ecological risk and/or endangered species risk; applicant initiated. 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	18	$137,198

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		species; applicant-initiated. (3)	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.		
A533	118	Exemption from the requirement of an Experimental Use Permit (2)	An application in which a request is made to exempt a new use from the requirements of an experimental use permit (EUP). New uses are defined within 40 CFR § 152.3	4	$3,559
A534	119	Rebuttal of agency reviewed protocol, applicant initiated	A submission to the EPA rebutting the conclusion(s) reached for a previously submitted study protocol. The science review of the study protocol is considered the completed PRIA decision. Any written response contesting the conclusions in the review is considered to be a separate action and subject to a separate fee under PRIA. This PRIA category applies to rebuttals of all protocol reviews (except HSRB protocol reviews), whether the original protocol was subject to PRIA or not.	4	$6,776
A535	120	Conditional Ruling on Pre-application Study Waiver or Data Bridging Argument; applicant-initiated	A voluntary pre-application request for a new active ingredient (a.i.) new use, or new product. The review requested is for a single study waiver associated with any of the above pre-applications. If multiple waivers are submitted the product will fail the technical screen. The study waiver request must include a written rationale for the study waiver, the identity of the active ingredient (chemical structure), and a draft label or explanation of the use pattern. The draft label submitted with this application is not subject to the Agency's approval under this category. If a waiver request or bridging argument is submitted for a new a.i., , EPA does not anticipate being able to grant the request because, if any exposures are expected to humans and/or the	6	$3,454

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			environment, studies providing information on the toxicity and fate and transport properties of the chemical are needed to support waiver and bridging argument requests. The Agency will not review the generic data normally associated with a new chemical application under this code. The application follows after the Agency has made a ruling on the study waiver(s). If a study waiver is denied, the application for the new use or new product can only be submitted once the study has been conducted and the applicant has a complete application for registration. If a study waiver is conditionally approved, the final decision on the waiver may be changed upon the review of the formal registration application and the data accompanying the application. Formal decisions or formal feedback on study waivers will not be made in any pre-submission meetings. New uses are defined within 40 CFR § 152.3. The ruling is subject to change if more/different information becomes available with the submission of a new product, or new use.		
A536	121	Conditional Ruling on Pre-application Direct Food, Indirect Food, Nonfood use determination; applicant-initiated	A pre-application request for new use, or new product. The request is for review of each direct, indirect or nonfood food determination associated with any of the above pre-applications. The fee for this category is for a single determination request. The request must include a written rationale for the proposed use determination, the identity of the active ingredient (chemical structure), and a draft label or explanation of the use pattern. A draft label submitted with this application is not subject to the Agency's approval under this category. The application follows after the Agency has made a ruling	4	$3,559

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			on the use determination(s). Once a determination is made, the application for the new use or new product can only be submitted once the appropriate studies have been conducted and the applicant has a complete application for registration. Once a decision on the use pattern has been made, the decision is conditional upon the review of the formal registration application and the data accompanying the application. Formal decisions or formal feedback on the proposed use pattern will not be made in any pre-submission meetings. If a waiver request or bridging argument is submitted for a new a.i., EPA does not anticipate being able to grant the request because, if any exposures are expected to humans and/or the environment, studies providing information on the toxicity and fate and transport properties of the chemical are needed to support waiver and bridging argument requests. The Agency will not review the generic data normally associated with a new chemical application under this code. New uses are defined within 40 CFR § 152.3. The ruling is subject to change if more/different information becomes available with the submission of a new product or new use.		
A575	122	Efficacy similarity determination; if two products can be bridged or if confirmatory efficacy data are needed.	An application for conditional ruling by EPA on the substantial similarity between a cited, registered product and a not-yet submitted new product or product amendment, as it relates to product efficacy data requirements and/or guidelines. The EPA response for this category is a letter indicating agreement/disagreement that the product cited by the applicant is substantially similar to an existing product, such that cited efficacy studies could adequately address product specific guideline requirements for the new product or amendment application when submitted. This is a conditional ruling, subject to change, should the actual registration or amendment application, once	4	$3,389

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			submitted, differ from the pre-application submission in formulation, labeling, or cited studies. Substantially similar: Product must have the same active ingredient(s), in the same proportion, same chemical composition (solid, liquid, granular and gas), and substantially similar inert ingredients as the already registered product that is being cited. In addition, an efficacy similarity decision means that the proposed product bears the same use patterns – based on use sites and product application. Efficacy claims made on the proposed label should be identical to those of the cited product. Adding use patterns or changing existing use patterns (other than deleting them) may exclude the proposed product from being found as substantially similar. A substantial similarity finding for other product-specific characteristics (e.g., acute toxicity and/or chemistry) is not a substitute for a similarity determination for efficacy. Conversely, substantial similarity in the efficacy context does not indicate definite substantial similarity in other scientific disciplines (e.g., acute toxicity and/or chemistry). To make the similarity determinations, documentation must be submitted to show the composition of the product and the uses. The following must be submitted, although additional items may be submitted as appropriate: • Confidential Statement of Formula(s) (CSF(s)); • Label(s); • Data matrix listing the specific studies being cited; • Cover letter identifying the EPA Reg. No. of the product being		

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			cited; and providing justification for the proposed similarity. The product that is being cited must be a registered product. This category does not contemplate multiple iterations of substantial similarity requests or rebuttal of the pre-conditional ruling on substantial similarity under the same application; each submission for efficacy similarity determination is managed independently. Any new proposal for citation to a different registered product must be submitted as a separate A575 application. This category does not contemplate multiple products being submitted for consideration of substantial similarity as part of one application. This determination is not required by the Agency as a pre-condition of a registration application, and such a request is at the discretion of the applicant.		

(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) 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.

3) 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.