PRIA 4 Interpretations

TABLE 10. ANTIMICROBIALS DIVISION - EXPERIMENTAL USE PERMITS AND OTHER TYPE OF ACTIONS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
A520	94	Experimental Use Permit application, non-food use (2)	Application for an experimental use permit for an active ingredient already (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 of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested 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.	9	6,703
A521	95	Review of public health efficacy	An application that requires the review of a modified protocol where only minor changes are	4	4,963

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		study protocol within AD; per AD internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; applicant initiated; Tier 1	made to an existing efficacy method (e.g. AOAC International, ASTM, AATCC, EPA guideline 810 or an AD approved method described in A431). 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 under this category. Examples of minor changes include: varied test conditions modification of standard method to support additional microorganisms [e.g., Germicidal Spray Products test for spore-formers], and changes to support alternate application types [e.g., foams]. 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 1. 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	96	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol and data review for devices making pesticidal claims; 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 assembled 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 is not subject to the Agency's approval 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	12,764
A537	97	New Active Ingredient/New	An Experimental Use Permit (EUP) application for direct food use(s) of an active ingredient	18	160,814

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
	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.	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 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.		
		New active	An Experimental Use Permit (EUP) application for a new indirect food use(s) of an active		

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A538	98 new	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	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 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.	18	100,511
A539	99 new	New active ingredient/new use Experimental	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	15	96,772

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		Use Permit application; nonfood use; credit 45% of fee toward new active ingredient/new use application that follows.	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 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.		
A529	100	Amendment to Experimental Use Permit; requires data review or risk assessment (2)	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 of the inerts used in the product must be either approved or pending with the Agency for	9	12,001

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			the applicable uses. The Agency will provide the applicant with a pre-decisional determination 2 weeks prior to the PRIA decision review time due date which specifies any label changes that have to be made in order to grant the requested 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.		
A523	101	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocol)	An application for approval of a study protocol submitted other than for public health organisms. 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 under this category.	9	12,764
A571	102	Science reassessment: Cancer risk, refined ecological risk, and/or endangered species; applicant-initiated	An application in which a request is made to change or refine the cancer classification or ecological risk; applicant initiated.	18	100,511
A533	103 new	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 40CFR part 152.3(p)	4	2,607
A534	104	Rebuttal of Agency reviewed	A submission to the EPA rebutting the conclusion(s) reached for a previously submitted study protocol. The science review of the study protocol is	4	4,963

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	new	protocol; applicant initiated	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.		
A535	105 new	Conditional ruling on Pre-application study waiver or data bridging argument; applicant initiated	A pre-application request for an active ingredient, new use, or new product. The request is for review of each study waiver associated with any of the above pre-applications. The fee for this category is for a single waiver request. The study waiver request must include a written rationale for the study waiver, the identity of the new 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. 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 active ingredient, 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 given approval, the final decision on the waiver is conditional 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 40CFR part 152.3(p)	6	2,530
A536	106 new	Conditional ruling on pre-application direct food, indirect food, nonfood use determination; applicant initiated	A pre-application request for an active ingredient, 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 new 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 on the use determination(s). Once a determination is made, the application for the new active ingredient, 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. New uses are defined within 40CFR part 152.3(p)	4	2,607