

PRIA 5 Interpretations

TABLE 6. REGISTRATION DIVISION (RD) - OTHER ACTIONS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)⁽¹⁾	FY'23-FY'24 Registration Service Fee (\$)
R124	75	Conditional Ruling on Pre-application Study Waivers; 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 multiplied by each additional waiver request submitted for review. The study waiver request must include a written rationale for the study waiver with an MRID assigned and the identity of the new active ingredient (chemical structure). 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. The 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 meetings such as pre-registration conferences, Dose Adequacy Response Team meetings (DART), or any other pre-registration meeting with the Agency.	6	3,627
R272	76	Review of Study Protocol applicant-initiated; excludes DART, pre-registration conference, Rapid Response review, DNT protocol review, protocol needing HSRB review, companion animal safety	An application for approval of a study protocol. Applicant provides a written copy of the protocol with an MRID assigned along with any specific questions about the protocol. The fee for this category is multiplied by each additional protocol submitted for review. This category does not include HSRB review and Companion Animal Safety protocol review (see M001 and R278, respectively). PRIA fees are not applicable for pre-submission or pre-registration conferences or discussions with the EPA such as Dose Adequacy Response Team (DART), EFED Rapid Response review, ChemSAC review, and DNT protocol reviews.	3	3,627

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) (1)	FY'23-FY'24 Registration Service Fee (\$)
		protocol			
R275	77	Rebuttal of agency reviewed protocol, applicant initiated	An application or submission to the EPA rebutting the conclusion(s) reached by the EPA for a previously submitted study protocol request. The science review of the study protocol is considered the completed PRIA decision on the protocol review request, so any written response contesting the conclusions in the review is considered to be a separate action and subject to a separate fee under PRIA. All documents submitted as part of the rebuttal/response must have an MRID assigned. This PRIA category applies to rebuttals of all protocol reviews (except HSRB protocol reviews), whether the original protocol was subject to PRIA or not. The fee for this category is multiplied by each rebuttal application that is submitted for review. PRIA fees are not applicable to pre-submission or pre-registration conferences or discussions with the EPA such as Dose Adequacy Response Team (DART), EFED Rapid Response Team, ChemSAC review, and DNT protocol reviews.	3	3,627
R278	78 (new)	Review of Protocol for companion animal safety study	<p>An application for approval of a companion animal safety study protocol. Applicant provides a written copy of the protocol with an MRID assigned along with supporting materials such as proposed label and any specific questions about the protocol to facilitate feedback on proposed claims such as minimum age, minimum weight, and dosage. The fee for this category is multiplied by each additional protocol submitted for review. A separate protocol must be submitted for kittens, for cats, for puppies, for dogs, for ferrets, etc. For example, a combined protocol for cats and kittens is not acceptable and each protocol will incur a separate fee.</p> <p>PRIA fees are not applicable for pre-submission or pre-registration conferences or discussions with the EPA.</p> <p>See PRIA category R275 for submitting questions or rebuttals to the Agency's review of companion animal safety protocol.</p>	5	4,927

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) <small>(1)</small>	FY'23-FY'24 Registration Service Fee (\$)
R279	79 (new)	Comparative product determination for reduced risk submission, applicant initiated; submitted before application for reduced risk new active ingredient or reduced risk new use	Prior to submission of a reduced risk registration application for a new conventional active ingredient or new conventional use (s) (R020, R070, R120, R160, R180, R200, R240, R270), the applicant may choose to submit a proposed list of comparable registered conventional active ingredients (by use site) to be used in reduced risk determination, along with a brief rationale for their selection. The submission should have an MRID assigned and include a clear description of the crop(s) or use site(s) for which reduced risk status is being requested, details of the proposed use pattern(s), and a list of proposed target pests to be used in the reduced risk assessment. EPA will respond to confirm or amend the list provided by the applicant and specify the data sources for use in the applicant's subsequent reduced risk registration application. EPA's list of comparable registered conventional active ingredients by use site will be applicable to the corresponding reduced risk application package so long as it is submitted by the registrant within 1 year of the date of EPA's response, notwithstanding potential changes to the comparable active ingredient list resulting from regulatory changes and/or changes to the target pest list or use pattern(s) that occur prior to the submission of the registration application.	3	5,200

(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.