

PRIA 4 Interpretations

TABLE 6. REGISTRATION DIVISION - OTHER ACTIONS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20- FY'21 Registration Service Fee (\$)
R124	67	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 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	2,657
R272	68	Review of Study Protocol	An application for approval of a study protocol. Applicant provides a written copy of	3	2,657

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		applicant-initiated; excludes DART, pre- registration conference, Rapid Response review, DNT protocol review, protocol needing HSRB review	the protocol along with any specific questions about the protocol. The fee for this category is multiplied by each additional protocol submitted for review. 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, DNT protocol reviews and HSRB review.		
R275	69	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. 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	3	2,657

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee (\$)
			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.		
R370	70	Cancer reassessment; applicant-initiated	An application which requests to change the cancer classification.	18	208,163