TABLE 7. ANTIMICROBIALS DIVISION (AD) - NEW ACTIVE INGREDIENTS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
A380	80	New Active Ingredient; indirect food use, establish tolerance or tolerance exemption if required (2) (3) (4)	An application that proposes an indirect food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. All uses included in any original application or petition for a new active ingredient or a first food use are covered by the base fee for that application in this category if submitted within the original application. 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 with 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 guidance applicable to this PRIA category. 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	26	239,355

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			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. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use 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, 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		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			without prejudice. The Antimicrobial Pesticide Use Site Index (USI) describes and provides examples of direct food, indirect food and nonfood uses for proposed applications. The USI also provides guidance to determine if proposed or labeled uses require the establishment of a tolerance or exemption from the requirement of a tolerance.		
A390	81	New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required (2) (3) (4)	An application that proposes a direct food use for an active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. All uses included in any original application or petition for a new active ingredient or a first food use are covered by the base fee for that application in this category if submitted simultaneously within the original application. 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 guidance applicable to this PRIA category. A maximum of five new products are covered by the base fee. After	26	345,729

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			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. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use 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, 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 the 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		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			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. The Antimicrobial Pesticide Use Site Index (USI) describes and provides examples of direct food, indirect food and nonfood uses for proposed applications. The USI also provides guidance to determine if proposed or labeled uses require the establishment of a tolerance or exemption from the requirement of a tolerance.		
A410	82	New Active Ingredient; Non-food use (2) (3) (4)	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. All non-food uses included in the original application or petition are covered by the base fee for that application in this category if submitted simultaneously within the original application. 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	23	292,592

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			screening. This extension is contingent on Agency issuing the ESA guidance applicable to this PRIA category. 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. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use 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, then the Agency will issue to the applicant its regulatory decision		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			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. The Antimicrobial Pesticide Use Site Index (USI) describes and provides examples of direct food, indirect food and nonfood uses for proposed applications. The USI also provides guidance to determine if proposed or labeled uses require the establishment of a tolerance or exemption from the requirement of a tolerance.		
A431	83	New Active Ingredient, Non-food use; indoor; low-risk (2) (3) (4)	An application that proposes a non-food use for a low risk active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. Active ingredients proposed as low risk will be considered on a case-by-case basis. Products that have any toxicity may result in the product being delayed to significant internal review processes. An application that proposes a non-food use for a low risk active ingredient. The product is not currently registered as an active ingredient in any U.S. registered pesticide product. All applications submitted under this code must provide a scientifically valid rationale as to why it should be considered a low risk active ingredient. Prior to submission a pre application meeting is highly recommended	14	120,734

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			to determine the product's category as a low risk. 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 guidance applicable to this PRIA category. 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.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'25-FY'26 Registration Service Fee ($)
			Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application. 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 new active ingredient registration. 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. 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. The Antimicrobial Pesticide Use Site Index (USI) describes and provides examples of direct food, indirect food and nonfood uses for proposed applications. The USI also provides guidance to determine if proposed or labeled uses require the establishment of a tolerance or exemption from the requirement of a tolerance.		

(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) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that 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 deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) 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.

(4) 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.