PRIA 4 Interpretations

TABLE 7. ANTIMICROBIALS DIVISION - NEW ACTIVE INGREDIENTS

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
A380	71	New Active Ingredient; indirect food use, establish tolerance or tolerance exemption if required (2) (3)	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 of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. 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. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be	24	144,734

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			charged an additional 25% of the full registration service fee for the new active ingredient 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 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. 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	72	New Active Ingredient; direct Food use; establish tolerance or tolerance exemption if required (2) (3)	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 of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses.	24	241,220

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			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. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient 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 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		

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			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	73	New Active Ingredient; Non-food use, (2) (3)	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 of the inerts used in the product must be either approved, pending with the Agency, or a new inert is submitted within the package for the applicable uses. 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. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be	21	241,262

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
			charged an additional 25% of the full registration service fee for the new active ingredient 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 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. 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	74	New Active Ingredient; Non-food use; low-risk; (2)(3)	An application that proposes a non-food use for a low risk/low toxicity active ingredient that is not currently contained as an active ingredient in any U.S. registered pesticide product. Active ingredients proposed as low risk/low toxicity will be considered on a case-by-case basis. All of the inerts used in the product must be either approved, pending with the Agency, or a	12	84,237

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			new inert is submitted within the package for the applicable uses. 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. If the applicant on his own initiative submits any additional information that was neither requested nor required by the Agency after completion of the technical deficiency screening, and which does not itself constitute a covered registration application, the applicant will be charged an additional 25% of the full registration service fee for the new active ingredient 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 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		

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			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.		