TABLE 8. ANTIMICROBIALS DIVISION (AD) - NEW USES

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [(1)]	FY'23-FY'24 Registration Service Fee ($)
A440	84	New Use, Indirect food use; establish tolerance or tolerance exemption (2) (3) (4) (6)	An application that proposes a new indirect food use. Up to five (5) uses included in any original application or petition for a first food use and to establish tolerance exemptions are covered by the base fee for that application in this category if submitted within the original application. Any use which either (1) requires the establishment or exemption from a tolerances, (2) is of a different use pattern (i.e. aquatic, terrestrial, outdoor, etc.) from what is currently registered, or (3) could result in the increase of exposure or a change in the route of exposure (ex. changes to application rate or changes to the application method) from that previously assessed by the agency, would be considered a new use (40 CFR 152.3). 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	23	$45,737

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			guidance applicable to this PRIA category. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product submitted in this package and/or new inert approval, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. 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. Finally, if the new use(s) application includes nonfood and food/indirect food uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the application.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			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 additional food use 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.		
A441	85	Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted	An application that proposes an additional indirect food use for an active ingredient with a current EPA registration. The application must propose six (6) or more specific additional indirect food uses. 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.	23	$164,639

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
		in one application (3) (4) (5) (6)	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. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product submitted in this package and/or new inert approval, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. 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		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			for the new active ingredient or first food use application. Finally, if the new use(s) application includes nonfood and food/indirect food uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the 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 additional food use 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.		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
A450	86	New use, Direct food use, establish tolerance or tolerance exemption (2) (3) (4) (6)	An application that proposes a new direct food use for an active ingredient with a current EPA registration. Any use which either (1) requires the establishment or exemption from a tolerances, (2) is of a different use pattern (i.e. aquatic, terrestrial, outdoor, etc.) from what is currently registered, or (3) could result in the increase of exposure or a change in the route of exposure (ex. changes to application rate or changes to the application method) from that previously assessed by the agency, would be considered a new use (40 CFR 152.3) 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. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product submitted in this package and/or new inert approval, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in	23	$137,198

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. 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. Finally, if the new use(s) application includes nonfood and food/indirect food uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the 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 additional food use 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		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			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.		
A451	87	Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application (3) (4) (5) (6)	An application that proposes an additional direct food use for an active ingredient with a current EPA registration. The application must propose six (6) or more specific new additional direct food uses. 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	22	$261,333

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			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. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product submitted in this package and/or new inert approval, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. 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. Finally, if the new use(s) application include non-food and food uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			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 use 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.		
A500	88	New use, non-food (4) (5) (6)	An application that proposes a non-food use for an active ingredient with a current EPA registration. The fee applies to each non-food use in this category requested in the application, up to 5 new uses. A different pattern of use that significantly changes or increases exposure such as a dosage rate increase or different method of	15	$45,737

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			application will result in the application being treated as a new use. 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. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product submitted in this package and/or new inert approval, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any use which either (1) requires the establishment or exemption from a tolerances, (2) is of a different use pattern (i.e. aquatic, terrestrial, outdoor, etc.) from what is currently registered, or (3) could result in the increase of exposure or a change in the route of exposure (ex. changes to application rate or changes to the application method)		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			from that previously assessed by the agency, would be considered a new use (40CFR 152.3) Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. 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. Finally, if the new use(s) application include non-food (indoor and/or outdoor) and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the 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 use 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		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			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.		
A501	89	New use, non-food; 6 or more submitted in one application (4) (5) (6)	An application that proposes a non-food use for an active ingredient with a current EPA registration. The application must propose six (6) or more specific new additional non-food indoor uses. Any use which either (1) requires the establishment or exemption from a tolerances, (2) is of a different use pattern (i.e. aquatic, terrestrial, outdoor, etc.) from what is currently registered, or (3) could result in the increase of exposure or a change in the route of exposure (ex. changes to application rate or changes to the application method) from that previously assessed by the agency, would be considered a new use (40 CFR 152.3). 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	17	$109,764

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			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. Amendment applications to add new use(s) to registered product labels are covered by the base fee for this category as long as they are all submitted in the same package. Each application for a new product submitted in this package and/or new inert approval, however, is subject to its own registration service fee. The only exception would be if the new use(s) were to be added only to a new product (no amendments to registered product labels in the application package) in which case the review of the one new product application would be covered by the base fee for the new uses. Any new product or amendment to the proposed labeling, which contains the same new use(s), that is submitted subsequent to the submission of the new use application but prior to its decision review time expiration date, will be deemed a separate new use application subject to a separate fee and new decision review time. 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		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			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. Finally, if the new use(s) application include nonfood and food uses, the appropriate fee is due for each type of new use, and the longest decision review time applies to all of the new uses requested in the 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 use 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		

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months) [1]	FY'23-FY'24 Registration Service Fee ($)
			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) If EPA data rules are amended to newly require clearance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

(4) 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.

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. 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 use application.

(6) 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.