PRIA 4 Interpretations

TABLE 8. ANTIMICROBIALS DIVISION - NEW USES

EPA No.	CR No.	Action	Interpretation	Decision Review Time (Months)	FY'20-FY'21 Registration Service Fee ($)
A440	75	New Use, indirect food use, establish tolerance or tolerance exemption (2) (3) (4)	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 (40CFR 152.3) All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. 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. 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	33,506

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 uses 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 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.		
A441	76	Additional indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application (3)(4)(5)	An application that proposes an additional indirect food use for an active ingredient with a current EPA registration. The application must propose at least six (6) or more specific additional indirect food uses. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. 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.	21	120,614

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			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. 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 uses 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 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.		
A450	77	New use; direct food use, establish tolerance or	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	21	100,511

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		tolerance exemption (2) (3) (4)	(40CFR 152.3) All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. 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. 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 uses 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 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.		

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			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	78	Additional direct food uses; establish tolerances or tolerance exemptions if required;6 or more submitted in one application (3) (4)(5)	An application that proposes an additional direct food use for an active ingredient with a current EPA registration. The application must propose at least six (6) or more specific new additional direct food uses. All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. 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. 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 use(s) 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 application.	21	191,452

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			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 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.		
A500	79	New use, non-food (4)(5)	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 application will result in the application being treated as a new use. 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) 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),	12	33,506

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			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. 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 use(s) 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 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.		
A501	80	New use, non-food; 6 or more submitted in one	An application that proposes a non-food use for an active ingredient with a current EPA registration. The application must propose at least six (6) or more specific new additional non-food indoor uses.	15	80,413

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		application (4)(5)	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 (40CFR 152.3) All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses. 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. 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 uses 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 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)		

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			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 to30 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.		