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A531 PRIA Fee Category

PRIA 4 Fee Determination Decision Tree:

Antimicrobial Active Ingredient Registration for End Use Product

Below is the fee for your selected Fee Category for Fiscal Years 2020-2021

Action Code	Description	FY'20-FY'21 Fee	Decision Time (months)
A531	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner. (2 <https://epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments#footnote2>) (3 <https://epa.gov/node/53623#footnote3>)	$1,916	4

Do you plan to request either of the following types of waivers <https://epa.gov/pria-fees/fee-waivers-and-exemptions>**?**

Waiver	Pay	Amount
50% waiver	You pay ---->>>>>	$958
75% waiver	You pay ---->>>>>	$479

PRIA Decision Tree

Go to the start of the Decision Tree <https://epa.gov/pria-fees/pria-4-fee-determination-decision-tree>

To pay the fee shown above, go to Paying PRIA Application Fees <https://epa.gov/node/46913/#methods> web page and follow the instructions.

How to submit your application directly to EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

Action Code Interpretation

Action Code Interpretation
An application for registration of an end-use pesticide product that is substantially similar or identical in its uses and/or formulation to products that are currently registered or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. The applicant must identify the similar products for all active ingredients in the proposed product. All applications require the following: • A data matrix is required with the application. • Product chemistry data (Group A and B) unless the product is identical. In some cases product chemistry data can be satisfied as outlined in PR Notice 98-1. • All inert ingredients must be already approved for the applicable uses in the product. • The source of the active ingredient must be currently registered (licensed) with the Agency. • In all cases, the applicant must identify the currently registered similar product for this category. • Acute toxicity, efficacy, public health pest efficacy, and/or child resistant packaging data requirement must be addressed by using: 1) the cite-all method, or 2) selective data citation where the applicant does not own all required data and does not have a specific authorization letter from the data owner. If a review of data other than product chemistry is needed, the application does not fall into this category. The application does not fall into this category if efficacy, acute toxicity, companion animal safety, and/or child resistant packaging data are submitted and must be reviewed to support the application. The application does not fall into this category if it contains a request to waive any of these data. An application that requires review of cited or submitted data other than product chemistry does not belong in this fee category. For the definition of a Substantially similar and Identical, please see category A530. An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient. 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 product 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.

Go to the start of the Decision Tree <https://epa.gov/pria-fees/pria-4-fee-determination-decision-tree>

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