



<http://www.epa.gov/pesticides/regulating/fees/related-apps.html>

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Pesticides: Regulating Pesticides

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Primary/Secondary (Related Applications)

PRIA 3 Primary/Secondary (Related Applications)

Primary/secondary is a term used by the Office of Pesticide Programs for a number of situations in which one or more applications or registration actions are dependent upon or related to another action. Because of the relationship, some actions may be grouped together in one application for which one fee is charged and in other cases, a discretionary refund may be available for the dependent or secondary action. Some of these situations were called parent/child relationships under PRIA 1. Primary/secondary relationships are described below for new active ingredients, uses, and products and amendments along with fees associated with the secondary actions and submission requirements.

Related Information

- [Data Requirements Checklists](#)
- [New and Amended Product Applications Associated with New Use Requests](#) (8 pp, 127k, About PDF)
- [Primary and Secondary New Product Applications](#) (8 pp, 130k, About PDF)

Questions on discretionary refunds should be directed to the [registration ombudsman](#) for the type of pesticide, i.e. conventional, antimicrobial or biopesticide. The ombudsman should also be consulted when a product is submitted that contains two or more different types of active ingredients such as a biological or a biochemical active ingredient combined with a conventional active ingredient. For information on primary/secondary [Plant Incorporated Protectant \(PIP\)](#) applications such as stacked PIPs, applicants should consult the [Biopesticides and Pollution Prevention Web site](#) or the Chief of the Microbial Pesticides Branch.

New Active Ingredients and First Food Use

The fee for an application to register a new active ingredient or first food use covers any application to register the active ingredient's technical (manufacturing use) and up to four end use products and any tolerance petitions submitted within the same application package. In the case of a new active ingredient application, 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 deemed 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 was neither requested nor required by the Agency and is submitted by the applicant at the applicant's own initiative to support the new active ingredient or first food use application will be assessed 25% of the registration service fee.

New Uses

The fee for the application is based on the number of new uses requested and includes (a) all label amendments to add the new uses to registered product labels and (b) the tolerance petitions submitted within the original application.

Any other amendment to a registered label besides adding the new use(s), its use directions and precautionary and advisory statements, is a separate registration action, subject to a separate fee for the corresponding PRIA category.

New Product Applications Submitted with New Use

Under PRIA 3 footnote #4 in Table 2, footnote #5 in Table 8, footnote #3 in Table 12 and footnote #5 in Table 15 state:

Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). ... Each application for an additional new product registration ... that is submitted in the new use application package is subject to the registration service fee for a new product... 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...

These footnotes change how the Agency will handle new product applications submitted with a new use under PRIA 3. If a new use application only proposes to register the new use for a new product and the application contains no amendment requests, review of the new product application is covered by the PRIA new-use fee. Any additional new products submitted in the same new use package are separate new product applications, each subject to an additional new product fee.

If a new use application amends one or more registered labels to add that new use, then any new product application submitted in the new use package with a request to add that same new use is considered a separate application, subject to a separate new product fee.

To assist applicants in identifying the appropriate fee for a secondary action submitted with a new use, applicants should consult the table, [New and Amended Product Applications Associated with New Use Requests](#) (8pp, 127k, [About PDF](#)), which also shows the Agency's system for tracking and linking related new product applications. The timeframe for a secondary application that is submitted along with the primary application is the same as that of the primary decision.

New Products

Each new product application is subject to a PRIA fee. If one set of data or data waivers, excluding product chemistry, pertains to two or more applications and the data and applications are submitted simultaneously, a discretionary refund may be granted to reduce the fee(s) for the secondary application(s) in accordance with FIFRA Section 33(b)(8)(C) to take into account the decreased amount of work required to review them.

In accordance with FIFRA 33(b)(2)(C), payment of at least 25% of the fee for the applicable PRIA category accompanied by a request for a refund of all or part of the remaining fee would allow this application to go forward to review. Based on previous years of experience, EPA expects that it can grant a discretionary refund that will likely result in a reduced fee as indicated in the [Primary and Secondary New Product Applications \(PDF\)](#) (8 pp, 130k, [About PDF](#)) table . Where this chart indicates the expected fee is more than 25%, EPA recommends submitting the amount of the expected fee as listed in this chart along with a request for a refund to avoid delays in processing applications for which a complete fee has not been received. To identify the likely fee for a secondary new product, applicants should consult the

table, [Primary and Secondary New Product Applications \(PDF\)](#) (8 pp, 130k), which also shows the Agency's system for tracking and linking related new product applications. The timeframe for the secondary decision is the same as that of the primary decision.

If the new product application relies on data with another application such as an amendment, and the two applications are not submitted within the same application, each of these applications is treated as an individual, separate application with its own fee, start date, and due date. The applicant must reference the data in the other application(s) and may request the discretionary refund.