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# Pesticide Registration Improvement Renewal Act (PRIA 2) Related Applications and Their Fees Primary and Secondary

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, fees are generally reduced 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.

Questions on fee reductions or 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 Pesticide \(PIP\)](#) 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 applications to register the active ingredient's technical (manufacturing use) and end use products and any tolerance petitions submitted simultaneously. "Simultaneously" means received by the Agency within 14 calendar days of the date that the initial submission is received by the Agency. Any associated action submitted more than 14 calendar days after that initial submission and while the application for the new active ingredient or first food use is still pending will be classified as a separate new active ingredient or first food use application and subject to the corresponding full new active ingredient or first food use PRIA fee and eligible for a FIFRA Section 33(b)(8)(C) discretionary refund which must be requested.

### Related Information

- [New Product Applications Submitted with New Use Requests](#) (5 pp, 40K, [About PDF](#))
- [Primary and Secondary New Product Applications](#) (3 pp, 35K, [About PDF](#))

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## 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 simultaneously. "Simultaneously" means received by the Agency within 14 calendar days of the date that the initial submission is received by the Agency. An additional related label amendment for that new use or other related action submitted more than 14 calendar days after the date of the initial submission and while the initial submission is still pending will be classified as a separate and additional new use application subject to the corresponding full new use PRIA fee and eligible for a FIFRA Section 33(b)(8)(C) discretionary refund which must be requested by the applicant.

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

If a new use application only proposes to register the new use for a new product, review of the new product application is covered by the PRIA new-use fee. Any additional new products submitted simultaneously are separate new product applications, each subject to at least an additional new use fee. However, the Agency will automatically apply FIFRA Section 33(b)(8)(C), the discretionary refund provision, to reduce the fee for these additional new product applications.

If a new use application amends at least one registered label to add that new use, then any new product application submitted simultaneously with a request to add that same new use is considered a separate application, subject to a separate new use fee. The Agency will automatically apply FIFRA Section 33(b)(8)(C), the discretionary refund provision, to reduce the fee for such a new product application.

To assist applicants in identifying the appropriate fee for a secondary action submitted with a new use, applicants should consult the table, [New Product Applications Submitted with New Use Requests](#) (5 pp, 40K, [About PDF](#)), 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.

## 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, the Agency applies the discretionary refund provision 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. The Agency furthermore will apply the refund at the time the applicant pays the fee to reduce the burden on registrants in paying a full fee and on the Agency in issuing refunds.

The application with the data is called the "primary" application or decision and the other applications dependent upon the primary's data submitted simultaneously with the primary are referred to as the secondary applications or decision. "Simultaneously" means received by the Agency within 14 calendar days of the date that the initial primary product submission is received by the Agency. If not submitted "simultaneously", the latter submission will not be deemed a secondary application, and a reduction in the fee will not be automatically considered and must be requested with a justification by the applicant. The primary application with the data must be submitted before or with the secondary applications; the secondary applications cannot be submitted prior to the primary application containing the data.

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

To identify the appropriate fee for a secondary new product, applicants should consult the table, [Primary and Secondary New Product Applications](#) (3 pp, 35K, [About PDF](#)) , 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.

## Amendments

When an applicant applies to amend a number of product labels with the same label language and submits a single set of data to support the change in the label language, it is considered one request with a single associated fee. The amendments **must be submitted in the same package** or envelope, and one set of data must apply to all of the amendments to qualify for a single amendment fee, otherwise, each amendment is a separate action with a separate fee.

## How the Agency keeps track of related applications/actions

Each type of action is tracked in the Agency's databases with each action identified by a decision (tracking) number in its database, and on pay.gov forms, invoices, and notifications of receipt. Each PRIA decision has a PRIA fee category

and decision review timeframe associated with it. The Agency uses a decimal system (i.e. A540.X) that follows the number of a PRIA fee category to identify secondary decisions, which applicants will observe on different forms of correspondence from the Agency. The decimal system allows the Agency to link primary and secondary decisions in its tracking system and to identify the fees associated with secondary decisions. The decimal system is also used to identify the number of uses in an application and the number of active ingredients in a product.

Type of Action	Fee	PRIA Tracking Code - Decimal
Primary	Fee of category	No decimal
Secondary	No Fee \$0.00	.0
	25% of fee	.1
Secondary new product with more than product chemistry – primary is new use amendment	Fee in table on new product applications submitted with new use requests	New use fee category.1
Secondary new product with more than product chemistry – primary is new product	Fee in New Products fee table	New Product Fee category.2
Two Active Ingredients in a Product	Per active ingredient	New ai fee category.2
Four uses requested for a registered active ingredient	Per use	New use fee category.4 (decimal shows number of uses)

**New Active Ingredients** - The application to register the technical (manufacturing use) product is generally designated as the primary decision and assigned the PRIA fee category and the fee appropriate for the fee category. The other components, i.e. end-use product applications and tolerance petition are considered secondary decisions.

**New Uses** - One application, generally a registered technical (manufacturing use) product, is designated as the “primary” decision and assigned the PRIA fee category and the fee appropriate for the fee category. The other components, e.g., label amendments proposing the new use directions and tolerance petition associated with the new use are considered secondary decisions. If a technical (manufacturing use) label is not submitted, the product with the highest concentration of active ingredient will be designated the “primary” submission.

**New Products and Amendments** - The application containing the data is designated as the primary decision. Other applications that are dependent on the same data are “secondary” decisions.

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