



Primary and Secondary New Product Applications, Submitted at the Same Time
(PC = Product Chemistry Data)
FY 2016/17 Fees

Description	Primary Application ¹		Secondary Application ²			
	PRIA Code	Application Fee (\$)	Where the only data submitted with a secondary application is product chemistry data or where the secondary application is a 100% repack of the primary		Where the secondary application contains more data than just PC such as efficacy and/or acute toxicity data	
			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
Registration Division						
New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or • public health pest efficacy and/or • child resistant packaging 	R310	5,301	R310.1	1,582	R310.2	5,301
New end use product containing two or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; requires review of data package within RD only; includes data and/or waivers of data for only: <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or • public health pest efficacy and/or 	R314	6,626	R314.1	1,657	R314.2	5,301

¹ Each new product application is subject to a PRIA fee. Where one set of data or data waivers apply to two or more new product applications that are submitted at the same time, the Agency refers to the first product application containing the data or data waivers as the primary application.

² Additional new product applications that rely on data or data waivers that were submitted with the primary product application are referred to as secondary applications.

³ EPA will assign a tracking code to alert reviewers to the relationship between primary and secondary applications. These codes are internal EPA tracking codes only.

⁴ Based on previous years of experience, EPA expects that it can grant a discretionary refund that will likely result in a reduced fee equal to the amount indicated in this column. This expected fee is based on either the fee for an identical/substantially similar product with no data review for the type of product (i.e. conventional, antimicrobial, or biopesticide) or 25% of the fee for the primary, whichever is greater and rounded up to the nearest whole dollar. 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 into review. **Where this chart indicates the expected fee is more than 25%, EPA recommends submitting the amount of the expected fee as listed in this column along with a request for a refund to avoid delays in processing applications for which a complete fee has not been received.**

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			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
• child resistant packaging						
New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: <ul style="list-style-type: none"> • product chemistry and/or • acute toxicity and/or • public health pest efficacy and/or • animal safety studies and/or • child resistant packaging 	R315	8,820	R315.1	2,205	R315.2	5,301
New product; new physical form; requires data review in science divisions	R320	13,226	R320.1	3,307	R320.2	5,301
New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only	R331	2,530	R331	N/A	R331	N/A
New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only ; requires review in RD and science divisions	R332	283,215	R332.1	70,804	R332.2	70,804
New product; MUP or end-use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data	R333	19,838	R333.1	4,961	R333.2	5,301
New product; MUP or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation.	R334	19,838	R334.1	4,961	R334.2	5,301
Antimicrobial Division						
New end use product; FIFRA §2(mm) uses only	A540	5,107	A540.1	1,277	A540.2	5,107
New end-use product; uses other than FIFRA §2(mm); non-FQPA product	A550	5,107	A550.1	1,277	A550.2	5,107

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			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
New manufacturing-use product; registered active ingredient; selective data citation	A560	19,146	A560.1	4,787	A560.2	5,107
Label amendment requiring data review	A570	3,831	A570.1	958	A570.2	3,831
Biopesticides and Pollution Prevention Division						
New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	B670	5,107	B670.1	1,216	B670.2	5,107
New product; unregistered source of active ingredient(s); requires a petition to amend an established tolerance or tolerance exemption; requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or	B671	12,764	B671.1	3,191	B671.2	5,107

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			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.						
New product; unregistered source of active ingredient(s); non-food use or food use with a tolerance or tolerance exemption previously established for the active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	B672	9,118	B672.1	2,280	B672.2	5,107
New product MUP/EP; unregistered source of active ingredient(s);	B673	5,107	B673.1	1,277	B673.2	5,107

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			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency. Requires an Agency determination that the cited data supports the new product.						
New Product MUP; registered source of active ingredient; submission of completely new generic data package; registered uses only.	B675	9,118	B675.1	2,280	B675.2	5,107
New product; more than one active ingredient where one active ingredient is an unregistered source; product chemistry data must be submitted; requires: 1) submission of product specific data, and 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply.	B676	9,118	B676.1	2,280	B676.2	5,107
New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only:	B677	8,820	B677.1	2,205	B677.2	5,107

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			Agency Code ³	Expected Fee ⁴ (\$)	Agency Code ³	Expected Fee ⁴ (\$)
<ul style="list-style-type: none"> - product chemistry and/or - acute toxicity and/or - public health pest efficacy and/or - animal safety studies and/or - child resistant packaging 						
New product; unregistered source of active ingredient (SCLP)	B721	2,676	B721.1	669	B721.2	2,676
Registration application; registered PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s).	B880	31,910	B880.1	7,978	B880.2	31,910
Registration application; registered PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). SAP review.	B881	95,724	B881.1	23,931	B881.2	95,724
Registration application; registered (3) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s).	B885	95,724	B885.1	23,931	B885.2	95,724

Example

A company submits 3 new antimicrobial registration applications. The 3 applications are: one 20% concentrate, a 15% concentrate and a 10% concentrate. The package consists of chemistry data for each application, one set of acute toxicity studies using the 20% concentrate and one set of efficacy data generated at the use dilution (the use dilution is the same for all three products). All three products will rely on the same efficacy data because all three products will be diluted to the same concentration and the difference in the inert ingredients is water.

Description of action	Expected Fee (\$)	Tracking Code
New product conc 20%	5,107	A540
New product conc 15%	1,277	A540.1
New product conc 10%	1,277	A540.1
Total Fee	7,661	