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21 U.S. Code § 379j-21

Authority to assess and use generic new animal drug fees

(a) Types of fees

Beginning with respect to fiscal year 2009, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Abbreviated application fee

(A) In general

Each person that submits, on or after July 1, 2008, an abbreviated application for a generic new animal drug shall be subject to a fee as established in subsection (c) for such an application.

(B) Payment

The fee required by subparagraph (A) shall be due upon submission of the abbreviated application.

(C) Exceptions

(i) Previously filed application

If an abbreviated application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an abbreviated application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(ii) Certain abbreviated applications involving combination animal drugs

An abbreviated application which is subject to the criteria in section 360b(d)(4) of this title and submitted on or after October 1, 2013 shall be subject to a fee equal to 50 percent of the amount of the abbreviated application fee established in subsection (c).

(D) Refund of fee if application refused for filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any abbreviated application which is refused for filing.

(E) Refund of fee if application withdrawn

If an abbreviated application is withdrawn after the application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

(2) Generic new animal drug product fee

(A) In general

Each person—

(i) who is named as the applicant in an abbreviated application or supplemental abbreviated application

for a generic new animal drug product which has been submitted for listing under section 360 of this title; and

(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application or supplemental abbreviated application,

shall pay for each such generic new animal drug product the annual fee established in subsection (c).

(B) Payment; fee due date

Such fee shall be payable for the fiscal year in which the generic new animal drug product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the generic new animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) Limitation

Such fee shall be paid only once for each generic new animal drug product for a fiscal year in which the fee is payable.

(3) Generic new animal drug sponsor fee

(A) In general

Each person—

(i) who meets the definition of a generic new animal drug sponsor within a fiscal year; and

(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application, a supplemental abbreviated application, or an investigational submission,

shall be assessed an annual generic new animal drug sponsor fee as established under subsection (c).

(B) Payment; fee due date

Such fee shall be due each fiscal year upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) Amount of fee

Each generic new animal drug sponsor shall pay only 1 such fee each fiscal year, as follows:

(i) 100 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 6 approved abbreviated applications.

(ii) 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

(iii) 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with 1 or fewer approved abbreviated applications.

(4) Generic investigational new animal drug file fee

(A) In general

(i) New file request

Each person that submits a request to establish a generic investigational new animal drug file on or after October 1, 2023, shall be assessed a fee as established under subsection (c).

(ii) New submission to established file

Each person that makes a submission to a generic investigational new animal drug file on or after October 1, 2023, where such file was established prior to October 1, 2023, shall be assessed a fee for the first submission on or after October 1, 2023, as established under subsection (c).

(B) Payment

(i) New file request

The fee required by subparagraph (A)(i) shall be due upon submission of the request to establish the generic investigational new animal drug file.

(ii) New submission to established file

The fee required by subparagraph (A)(ii) shall be due upon the first submission to the generic investigational new animal drug file.

(C) Exceptions

(i) Terminating an existing generic investigational new animal drug file

If a person makes a submission to the generic investigational new animal drug file to terminate that file, the person shall not be subject to a fee under subparagraph (A)(ii) for that submission.

(ii) Transferring an existing generic investigational new animal drug file

If a person makes a submission to the generic investigational new animal drug file to transfer that file to a different generic new animal drug sponsor, the person shall not be subject to a fee under subparagraph (A)(ii) for that submission.