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21 U.S. Code § 379h

Authority to assess and use drug fees

(a) Types of fees

Beginning in fiscal year 2023, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Human drug application fee

(A) In general

Each person that submits, on or after September 1, 1992, a human drug application shall be subject to a fee as follows:

(i) A fee established under subsection (c)(6) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection (c)(6) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval. Such fee shall be half of the amount of the fee established under clause (i).

(B) Payment

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

(C) Exception for previously filed application

If a human drug application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn prior to approval (without a waiver), the submission of a human drug application for the same product by the same person (or the person's licensee, assignee,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).

(D) Refund of fee if application refused for filing or withdrawn before filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application which is refused for filing or withdrawn without a waiver before filing.

(E) Fees for applications previously refused for filing or withdrawn before filing

A human drug application that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).

(F) Exception for designated orphan drug

A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 360bb of this title shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition.

(G) Refund of fee if application withdrawn

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

(H) Exception for skin-test diagnostic products

A human drug application for a skin-test diagnostic product shall not be subject to a fee under subparagraph (A).

(2) Prescription drug program fee

(A) In general

(i) Payment of fees

Except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year. Such fee shall be due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

(ii) Special rule for previously discontinued drug products

If a drug product that is identified in a human drug application approved as of October 1 of a fiscal year is not a prescription drug product as of that date because the drug product is in the discontinued section of a list referenced in section 379g(3)(A)(iii) of this title, and on any subsequent day during such fiscal year the drug product is a prescription drug product, then except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application with respect to such product, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for such prescription drug product. Such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for a fiscal year in which the fee is payable.

(B) Exception for certain prescription drug products

A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—

(i) a large volume parenteral product (a sterile aqueous drug product packaged in a single-dose container with a volume greater than or equal to 100 mL, not including powders for reconstitution or pharmacy bulk packages) identified on the list compiled under section 355(j)(7) of this title;

(ii) pharmaceutically equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulation)) to another product on the list of products compiled under section 355(j)(7) of this title (not including the discontinued section of such list); or

(iii) a skin-test diagnostic product.

(C) Limitation

A person who is named as the applicant in an approved human drug application shall not be assessed

more than 5 prescription drug program fees for a fiscal year for prescription drug products identified in such approved human drug application.