
21 U.S. Code § 379j-52

Authority to assess and use biosimilar biological product 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) Biosimilar biological product development program fees

(A) Initial biosimilar biological product development fee

(i) In general

Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection (c)(5).

(ii) Meeting request

The meeting request described in this clause is a request for a biosimilar biological product development meeting for a product.

(iii) Clinical protocol for IND

A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 355(i) of this title, including any regulations promulgated under section 355(i) of this title, (referred to in this section as “investigational new drug application”) describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

(iv) Due date

The initial biosimilar biological product development fee shall be due by the earlier of the following:

(I) Not later than 7 days after the Secretary grants a request for a biosimilar biological product development meeting.

(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application.

(v) Transition rule

Each person that has submitted an investigational new drug application prior to July 9, 2012, shall pay the initial biosimilar biological product development fee by the earlier of the following:

(I) Not later than 60 days after July 9, 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application.

(II) Not later than 7 days after the Secretary grants a request for a biosimilar biological product development meeting.

(B) Annual biosimilar biological product development fee

(i) In general

A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (c)(5) for the biosimilar biological product development program (referred to in this section as “annual biosimilar biological product development fee”), except that, in the case that such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.

(ii) Due date

The annual biosimilar biological product development fee for each fiscal year will be due on the later of—

- (I) the first business day on or after October 1 of each such year; or
- (II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(iii) Exception

The annual biosimilar biological product development fee for each fiscal year will be due on the date specified in clause (ii), unless the person has—

- (I) submitted a marketing application for the biological product that was accepted for filing;
- (II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C); or
- (III) been administratively removed from the biosimilar biological product development program for the product under subparagraph (E)(v).

(iv) Refund

If a person submits a marketing application for a biosimilar biological product before October 1 of a fiscal year and such application is subsequently accepted for filing, the person may request a refund equal to the annual biosimilar biological product development fee paid by the person for the product for such fiscal year. To qualify for consideration for a refund under this clause, a person shall submit to the Secretary a written request for such refund not later than 180 days after the marketing application is accepted for filing.

(C) Discontinuation of fee obligation

A person may discontinue participation in the biosimilar biological product development program for a product, effective October 1 of a fiscal year, by, not later than August 1 of the preceding fiscal year—

- (i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product; or
- (ii) if an investigational new drug application concerning the product has been submitted, withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

(D) Reactivation fee

(i) In general

A person that has discontinued participation in the biosimilar biological product development program

for a product under subparagraph (C), or who has been administratively removed from such program for a product under subparagraph (E)(v), shall, if the person seeks to resume participation in such program, pay all annual biosimilar biological product development fees previously assessed for such product and still owed and a fee (referred to in this section as “reactivation fee”) by the earlier of the following:

(I) Not later than 7 days after the Secretary grants a request by such person for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued or the date of administrative removal, as applicable).

(II) Upon the date of submission (after the date on which such participation was discontinued or the date of administrative removal, as applicable) by such person of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

(ii) Application of annual fee

A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B), except that, in the case that such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.

(E) Effect of failure to pay fees

(i) No biosimilar biological product development meetings

If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

(ii) No receipt of investigational new drug applications

Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 355(i)(2) of this title if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iii) Financial hold

Notwithstanding section 355(i)(2) of this title, except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

(iv) No acceptance of biosimilar biological product applications or supplements

If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any

biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(v) Administrative removal from the biosimilar biological product development program

If a person has failed to pay an annual biosimilar biological product development fee for a product as required under subparagraph (B) for a period of 2 consecutive fiscal years, the Secretary may administratively remove such person from the biosimilar biological product development program for the product. At least 30 days prior to administratively removing a person from the biosimilar biological product development program for a product under this clause, the Secretary shall provide written notice to such person of the intended administrative removal.

(F) Limits regarding fees

(i) Refunds

Except as provided in subparagraph (B)(iv), the Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).

(ii) No waivers, exemptions, or reductions

The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

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