licly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) Content

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(June 25, 1938, ch. 675, §740A, as added Pub. L. 110–316, title I, §104, Aug. 14, 2008, 122 Stat. 3511; amended Pub. L. 113–14, title I, §104, June 13, 2013, 127 Stat. 462; Pub. L. 115–234, title I, §104, Aug. 14, 2018, 132 Stat. 2431; Pub. L. 118–15, div. B, title III, §2304, Sept. 30, 2023, 137 Stat. 89.)

TERMINATION OF SECTION

For termination of section by section 2307(b) of Pub. L. 118–15, see Effective and Termination Dates note below.

Editorial Notes

REFERENCES IN TEXT

Section 101(b) of the Animal Drug User Fee Amendments of 2023, referred to in subsec. (a), probably should be a reference to section 2301(b) of the Animal Drug User Fee Amendments of 2023, chapter 1 of subtitle A of title III of div. B of Pub. L. 118–15, which is set out as a note under section 379j–11 of this title. The Animal Drug User Fee Amendments of 2023 does not contain a section 101(b).

AMENDMENTS

2023—Subsec. (a). Pub. L. 118–15, §2304(1), (2), substituted ''2024'' for ''2019'' and ''2023'' for ''2018''.

Subsec. (b). Pub. L. 118–15, §2304(2), substituted ''2024'' for ''2019''.

Subsec. (d)(1), (5). Pub. L. 118–15, §2304(3), substituted ''2028'' for ''2023''.

2018—Subsec. (a). Pub. L. 115–234, §104(1), (2), substituted ''2019'' for ''2014'' and ''2018'' for ''2013''.

Subsec. (b). Pub. L. 115–234, §104(2), substituted ''2019'' for ''2014''.

Subsec. (d)(1), (5). Pub. L. 115–234, §104(3), substituted ''2023'' for ''2018''.

2013—Pub. L. 113–14 amended section generally. Prior to amendment, section related to reauthorization of this subpart and reporting requirements.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2023 AMENDMENT

Amendment by Pub. L. 118–15 effective Oct. 1, 2023, and fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as amended, to be assessed for animal drug applications and supplemental animal drug applications received on or after Oct. 1, 2023, see section 2306 of Pub. L. 118–15, set out as a note under section 379j–11 of this title.

EFFECTIVE DATE OF 2018 AMENDMENT

Amendment by Pub. L. 115–234 effective Oct. 1, 2018, and fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.) to be assessed for animal drug applications and supplemental animal drug applications received on or after Oct. 1, 2018, see section 106 of Pub. L. 115–234, set out as a note under section 379j–11 of this title.

EFFECTIVE DATE OF 2013 AMENDMENT

Amendment by Pub. L. 113–14 effective Oct. 1, 2013, see section 106 of Pub. L. 113–14, set out as a note under section 379j–11 of this title.

EFFECTIVE AND TERMINATION DATES

Pub. L. 118–15, div. B, title III, §2307(b), Sept. 30, 2023, 137 Stat. 89, provided that: ''Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) shall cease to be effective January 31, 2029.''

Pub. L. 115–234, title I, §107(b), Aug. 14, 2018, 132 Stat. 2432, which provided that section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) would cease to be effective Jan. 31, 2024, was repealed by Pub. L. 118–15, div. B, title III, §2307(c), Sept. 30, 2023, 137 Stat. 89, effective Oct. 1, 2023.

Pub. L. 113–14, title I, §107(b), June 13, 2013, 127 Stat. 464, which provided that section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) would cease to be effective Jan. 31, 2019, was repealed by Pub. L. 115–234, title I, §107(c), Aug. 14, 2018, 132 Stat. 2432, effective Oct. 1, 2018.

Section effective Oct. 1, 2008, with fees under this subpart to be assessed for all animal drug applications and supplemental animal drug applications received on or after Oct. 1, 2008, see section 107 of Pub. L. 110–316, set out as an Effective and Termination Dates of 2008 Amendment note under section 379j–11 of this title.

SUBPART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS

TERMINATION OF SUBPART

For termination of subpart by section 2316(a), (b) of Pub. L. 118–15, see Termination Date notes set out under sections 379j–21 and 379j–22 of this title.

§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.

(b) Fee revenue amounts

(1) In general

Subject to subsections (c), (d), (f), and (g), for each of fiscal years 2024 through 2028, the fees required under subsection (a) shall be established to generate a total revenue amount of $25,000,000.

(2) Types of fees

Of the total revenue amount established for a fiscal year under paragraph (1)—

(A) 20 percent shall be derived from fees under subsection (a)(1) (relating to abbreviated applications for a generic new animal drug) and fees under subsection (a)(4) (relating to generic investigational new animal drug files);

(B) 40 percent shall be derived from fees under subsection (a)(2) (relating to generic new animal drug products); and

(C) 40 percent shall be derived from fees under subsection (a)(3) (relating to generic new animal drug sponsors).

(c) Annual fee setting; adjustments

(1) Annual fee setting

The Secretary shall establish, not later than 60 days before the start of each fiscal year beginning after September 30, 2023, for that fiscal year—

(A) abbreviated application fees that are based on the revenue amounts established under subsection (b), the adjustments provided under this subsection, and the amount of fees anticipated to be collected under subsection (a)(4) during that fiscal year;

(B) generic new animal drug sponsor fees, and generic new animal drug product fees, based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

(C) a generic investigational new animal drug file fee of $50,000 for each request or submission described in subsection (a)(4)(A).

(2) Inflation adjustment

(A) In general

For fiscal year 2025 and subsequent fiscal years, the revenue amounts established under subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by multiplying such revenue amounts by an amount equal to the sum of—

(i) one;

(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 of the preceding 4 fiscal years for which data are available; and

(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 of the preceding 4 fiscal years for which data are available.

(B) Compounded basis

The adjustment made each fiscal year after fiscal year 2025 under this paragraph shall be applied on a compounded basis to the revenue amount calculated under this paragraph for the most recent previous fiscal year.

(3) Workload adjustments

(A) In general

For fiscal year 2025 and subsequent fiscal years, after the fee revenue amounts established under subsection (b) are adjusted for inflation in accordance with paragraph (2), the fee revenue amounts shall be further adjusted for each such fiscal year to reflect changes in the workload of the Secretary for the process for the review of abbreviated applications for generic new animal drugs, subject to subparagraphs (B) and (C). With respect to such adjustment—

(i) this adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, investigational generic new animal drug protocol submissions, requests to establish a generic investigational new animal drug file, and generic investigational new animal drug meeting requests submitted to the Secretary;

(ii) if the workload adjustment calculated by the Secretary under clause (i) exceeds 25 percent, the Secretary shall use 25 percent for the adjustment; and

(iii) the Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

(B) Reduction of workload-based increase by amount of certain excess collections

For each of fiscal years 2026 through 2028, if application of the workload adjustment under subparagraph (A) increases the fee revenue amounts otherwise established for the fiscal year under subsection (b), as adjusted for inflation under paragraph (2), such fee revenue increase shall be reduced by the amount of any excess collections, as described in subsection (g)(4), for the second preceding fiscal year, up to the amount of such fee revenue increase.

(C) Rule of application

Under no circumstances shall workload adjustments under this paragraph result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established under subsection (b), as adjusted for inflation under paragraph (2).

(4) Final year adjustment

For fiscal year 2028, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of fiscal year 2029. If the Food and Drug Administration has carryover balances for the process for the review of abbreviated applications for generic new animal drugs in excess of 3 months of such operating reserves, then this adjustment shall not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2028.

(5) Limit

The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of abbreviated applications for generic new animal drugs.

(d) Fee waiver or reduction

The Secretary shall grant a waiver from, or a reduction of, one or more fees assessed under subsection (a) where the Secretary finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.

(e) Effect of failure to pay fees

An abbreviated application for a generic new animal drug submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational submission for a generic new animal drug that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. A request to establish a generic investigational new animal drug file that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for action by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

(f) Assessment of fees

(1) Limitation

Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) Authority

If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for abbreviated applications, generic new animal drug products, generic new animal drug sponsors, and generic investigational new animal drug files at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) Crediting and availability of fees

(1) In general

Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of abbreviated applications for generic new animal drugs.

(2) Collections and appropriation Acts

(A) In general

The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2008 multiplied by the adjustment factor.

(B) Compliance

The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of abbreviated applications for generic new animal drugs—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

(C) Provision for early payments

Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) Authorization of appropriations

For each of the fiscal years 2024 through 2028, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount established under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c).

(4) Excess collections

If the sum total of fees collected under this section for a fiscal year exceeds the amount of fees authorized to be appropriated for such year under paragraph (3), the excess collections shall be credited to the appropriations account of the Food and Drug Administration as provided in paragraph (1).

(5) Recovery of collection shortfalls

The amount of fees otherwise authorized to be collected under this section shall be increased—

(A) for fiscal year 2026, by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2024 falls below the amount of fees authorized for fiscal year 2024 under paragraph (3);

(B) for fiscal year 2027, by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2025 falls below the amount of fees authorized for fiscal year 2025 under paragraph (3); and

(C) for fiscal year 2028, by the amount, if any, by which the amount collected under this section and appropriated for fiscal years 2026 and 2027 (including estimated collections for fiscal year 2027) falls below the amount of fees authorized for such fiscal years under paragraph (3).

(h) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(i) Written requests for waivers, reductions, and refunds

To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) Construction

This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of abbreviated applications for generic new animal drugs, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) Definitions

In this section and section 379j–22 of this title:

(1) Abbreviated application for a generic new animal drug

The terms ''abbreviated application for a generic new animal drug'' and ''abbreviated application'' mean an abbreviated application for the approval of any generic new animal drug submitted under section 360b(b)(2) of this title. Such term does not include a supplemental abbreviated application for a generic new animal drug.

(2) Adjustment factor

The term ''adjustment factor'' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by—

(A) for purposes of subsection (f)(1), such Index for October 2002; and

(B) for purposes of subsection (g)(2)(A)(ii), such Index for October 2007.

(3) Costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs

The term ''costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs'' means the expenses in connection with the process for the review of abbreviated applications for generic new animal drugs for—

(A) officers and employees of the Food and Drug Administration, contractors of the

Food and Drug Administration, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees under this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(4) Final dosage form

The term ''final dosage form'' means, with respect to a generic new animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes generic new animal drug products intended for mixing in animal feeds.

(5) Generic new animal drug

The term ''generic new animal drug'' means a new animal drug that is the subject of an abbreviated application.

(6) Generic new animal drug product

The term ''generic new animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or a supplemental abbreviated application has been approved.

(7) Generic new animal drug sponsor

The term ''generic new animal drug sponsor'' means either an applicant named in an abbreviated application for a generic new animal drug that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive by the Secretary.

(8) Generic investigational new animal drug meeting request

The term ''generic investigational new animal drug meeting request'' means a request submitted by a generic new animal drug sponsor to meet with the Secretary to discuss an investigational submission for a generic new animal drug.

(9) Investigational submission for a generic new animal drug

The terms ''investigational submission for a generic new animal drug'' and ''investigational submission'' mean—

(A) the filing of a claim for an investigational exemption under section 360b(j) of this title for a generic new animal drug intended to be the subject of an abbreviated application or a supplemental abbreviated application; or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of a generic new animal drug in the event of the filing of an abbreviated application or supplemental abbreviated application for such drug.

(10) Person

The term ''person'' includes an affiliate thereof (as such term is defined in section 379g(11) of this title).

(11) Process for the review of abbreviated applications for generic new animal drugs

The term ''process for the review of abbreviated applications for generic new animal drugs'' means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:

(A) The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(B) The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval.

(C) The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary's review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(D) Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(E) The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the generic new animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.

(I) The activities necessary for exploration and implementation of the United States and European Union Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections, and the United States and United Kingdom Mutual Recognition Agreement Sectoral Annex for Pharmaceutical Good Manufacturing Practices, and other mutual recognition agree-

ments, with respect to generic new animal drug products subject to review, including implementation activities prior to and following product approval.

(12) Request to establish a generic investigational new animal drug file

The term ''request to establish a generic investigational new animal drug file'' means the submission to the Secretary of a request to establish a generic investigational new animal drug file to contain investigational submissions for a generic new animal drug.

(13) Supplemental abbreviated application for generic new animal drug

The terms ''supplemental abbreviated application for a generic new animal drug'' and ''supplemental abbreviated application'' mean a request to the Secretary to approve a change in an approved abbreviated application.

(June 25, 1938, ch. 675, §741, as added Pub. L. 110–316, title II, §202(b), Aug. 14, 2008, 122 Stat. 3515; amended Pub. L. 113–14, title II, §202, June 13, 2013, 127 Stat. 465; Pub. L. 115–234, title II, §202, Aug. 14, 2018, 132 Stat. 2432; Pub. L. 118–15, div. B, title III, §2312, Sept. 30, 2023, 137 Stat. 90.)

TERMINATION OF SECTION

For termination of section by section 2316(a) of Pub. L. 118–15, see Termination Date note below.

Editorial Notes

PRIOR PROVISIONS

A prior section 741 of act June 25, 1938, was renumbered section 745 and is classified to section 379k of this title.

AMENDMENTS

2023—Subsec. (a)(4). Pub. L. 118–15, §2312(a), added par. (4).

Subsec. (b)(1). Pub. L. 118–15, §2312(b)(1), substituted ''2024 through 2028'' for ''2019 through 2023'' and ''$25,000,000'' for ''$18,336,340''.

Subsec. (b)(2)(A). Pub. L. 118–15, §2312(b)(2)(A), substituted ''20 percent'' for ''25 percent'' and inserted before semicolon at end ''and fees under subsection (a)(4) (relating to generic investigational new animal drug files)''.

Subsec. (b)(2)(B), (C). Pub. L. 118–15, §2312(b)(2)(B), (C), substituted ''40 percent'' for ''37.5 percent''.

Subsec. (c)(1). Pub. L. 118–15, §2312(c)(1), amended par. (1) generally. Prior to amendment, text read as follows: ''The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2008, for that fiscal year, abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees, based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.''

Subsec. (c)(2)(A). Pub. L. 118–15, §2312(c)(2)(A), substituted ''2025'' for ''2020'' in introductory provisions.

Subsec. (c)(2)(A)(iii). Pub. L. 118–15, §2312(c)(2)(A)(ii), substituted ''Arlington-Alexandria'' for ''Baltimore''.

Subsec. (c)(2)(B). Pub. L. 118–15, §2312(c)(2)(B), substituted ''2025'' for ''2020''.

Subsec. (c)(3)(A). Pub. L. 118–15, §2312(c)(3)(A)(i), substituted ''2025'' for ''2020'' in introductory provisions.

Subsec. (c)(3)(A)(i). Pub. L. 118–15, §2312(c)(3)(A)(ii)(I), substituted ''investigational generic new animal drug protocol submissions, requests to establish a generic investigational new animal drug file, and generic investigational new animal drug meeting requests'' for ''and investigational generic new animal drug protocol submissions''.

Subsec. (c)(3)(A)(ii), (iii). Pub. L. 118–15, §2312(c)(3)(A)(ii)(II)–(iv), added cl. (ii) and redesignated former cl. (ii) as (iii).

Subsec. (c)(3)(B). Pub. L. 118–15, §2312(c)(3)(B), substituted ''2026 through 2028'' for ''2021 through 2023''.

Subsec. (c)(4). Pub. L. 118–15, §2312(c)(4), substituted ''2028'' for ''2023'' in two places and ''2029'' for ''2024''.

Subsec. (d). Pub. L. 118–15, §2312(d), amended subsec. (d) generally. Prior to amendment, subsec. (d) related to fee waiver or reduction and exemption from fees.

Subsec. (e). Pub. L. 118–15, §2312(e), substituted ''A request to establish a generic investigational new animal drug file that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for action by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue'' for ''The Secretary may discontinue''.

Subsec. (f)(2). Pub. L. 118–15, §2312(f), substituted ''products, generic new animal drug sponsors, and generic investigational new animal drug files at any time'' for ''sponsors, and generic new animal drug products at any time''.

Subsec. (g)(3). Pub. L. 118–15, §2312(g)(1), substituted ''2024 through 2028'' for ''2019 through 2023''.

Subsec. (g)(4). Pub. L. 118–15, §2312(g)(2), struck out par. (4) relating to offset. Text read as follows: ''If the sum of the cumulative amount of fees collected under this section for the fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.''

Subsec. (g)(5). Pub. L. 118–15, §2312(g)(3), added par. (5).

Subsec. (k)(8) to (11). Pub. L. 118–15, §2312(h)(1), (2), added par. (8) and redesignated former pars. (8) to (10) as (9) to (11), respectively. Former par. (11) redesignated (13).

Subsec. (k)(11)(I). Pub. L. 118–15, §2312(h)(3), added subpar. (I).

Subsec. (k)(12), (13). Pub. L. 118–15, §2312(h)(1), (4), added par. (12) and redesignated par. (11) as (13).

2018—Subsec. (b). Pub. L. 115–234, §202(a), amended subsec. (b) generally. Prior to amendment, subsec. (b) related to fee amounts for fiscal years 2014 to 2018.

Subsec. (c)(2). Pub. L. 115–234, §202(b)(1)(B), added par. (2). Former par. (2) redesignated (3).

Subsec. (c)(3). Pub. L. 115–234, §202(b)(1)(A), (2), redesignated par. (2) as (3) and amended it generally. Prior to amendment, text read as follows: ''The fee revenues shall be adjusted each fiscal year after fiscal year 2014 to reflect changes in review workload. With respect to such adjustment:

''(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

''(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b).''

Former par. (3) redesignated (4).

Subsec. (c)(4). Pub. L. 115–234, §202(b)(1)(A), (3), redesignated par. (3) as (4) and substituted ''2023'' for ''2018''

in two places and ''2024'' for ''2019''. Former par. (4) redesignated (5).

Subsec. (c)(5). Pub. L. 115–234, § 202(b)(1)(A), redesignated par. (4) as (5).

Subsec. (d). Pub. L. 115–234, § 202(c), amended subsec. (d) generally. Prior to amendment, text read as follows: ''The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.''

Subsec. (g)(3), (4). Pub. L. 115–234, § 202(d), added par. (3) and par. (4) relating to excess collections and struck out former par. (3) which related to authorization of appropriations for fiscal years 2014 to 2018.

2013—Pub. L. 113–14 amended section generally. Prior to amendment, section related to authority to assess and use generic new animal drug fees.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2023 AMENDMENT

Pub. L. 118–15, div. B, title III, § 2315, Sept. 30, 2023, 137 Stat. 94, provided that: ''The amendments made by this chapter [chapter 2 (§§ 2311–2316) of subtitle A of title III of div. B of Pub. L. 118–15, amending this section and section 379j–22 of this title and repealing provisions set out as notes under this section and section 379j–22 of this title] shall take effect on October 1, 2023, or the date of the enactment of this Act [Sept. 30, 2023], whichever is later, except that fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as amended by this chapter, shall be assessed for abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after October 1, 2023, regardless of the date of enactment of this Act.''

EFFECTIVE DATE OF 2018 AMENDMENT

Pub. L. 115–234, title II, § 205, Aug. 14, 2018, 132 Stat. 2435, provided that: ''The amendments made by this title [see section 201(a) of Pub. L. 115–234, set out as a Short Title of 2018 Amendment note under section 301 of this title] shall take effect on October 1, 2018, or the date of the enactment of this Act [Aug. 14, 2018], whichever is later, except that fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–21 et seq.], as amended by this title, shall be assessed for abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after October 1, 2018, regardless of the date of enactment of this Act.''

EFFECTIVE DATE OF 2013 AMENDMENT

Pub. L. 113–14, title II, § 205, June 13, 2013, 127 Stat. 474, provided that: ''The amendments made by this title [amending this section and section 379j–22 of this title and repealing provisions set out as notes under this section and section 379j–22 of this title] shall take effect on October 1, 2013, or the date of enactment of this Act [June 13, 2013], whichever is later, except that fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–21 et seq.], as amended by this title, shall be assessed for all abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after October 1, 2013, regardless of the date of enactment of this Act.''

TERMINATION DATE

Pub. L. 118–15, div. B, title III, § 2316(a), Sept. 30, 2023, 137 Stat. 94, provided that: ''Section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall cease to be effective October 1, 2028.''

Pub. L. 115–234, title II, § 206(a), Aug. 14, 2018, 132 Stat. 2435, which provided that section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) would cease to be effective Oct. 1, 2023, was repealed by Pub. L. 118–15, div. B, title III, § 2316(c), Sept. 30, 2023, 137 Stat. 94, effective Oct. 1, 2023.

Pub. L. 113–14, title II, § 206(a), June 13, 2013, 127 Stat. 474, which provided that section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) would cease to be effective Oct. 1, 2018, was repealed by Pub. L. 115–234, title II, § 206(c), Aug. 14, 2018, 132 Stat. 2435, effective Oct. 1, 2018.

Pub. L. 110–316, title II, § 204(a), Aug. 14, 2008, 122 Stat. 3524, which provided that the amendments made by section 202 of Pub. L. 110–316 (enacting this section and amending sections 379k, 379*l*, and 379*o* of this title) would cease to be effective Oct. 1, 2013, was repealed by Pub. L. 113–14, title II, § 206(c)(1), June 13, 2013, 127 Stat. 474.

SAVINGS PROVISIONS

Pub. L. 118–15, div. B, title III, § 2314, Sept. 30, 2023, 137 Stat. 94, provided that: ''Notwithstanding the amendments made by this chapter [chapter 2 (§§ 2311–2316) of subtitle A of title III of div. B of Pub. L. 118–15, amending this section and section 379j–22 of this title and repealing provisions set out as notes under this section and section 379j–22 of this title], part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as in effect on the day before the date of enactment of this chapter [Sept. 30, 2023], shall continue to be in effect with respect to abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug (as defined in such part as of such day) that on or after October 1, 2018, but before October 1, 2023, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2024.''

Pub. L. 115–234, title II, § 204, Aug. 14, 2018, 132 Stat. 2435, provided that: ''Notwithstanding the amendments made by this title [see section 201(a) of Pub. L. 115–234, set out as a Short Title of 2018 Amendment note under section 301 of this title], part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as in effect on the day before the date of enactment of this title [Aug. 14, 2018], shall continue to be in effect with respect to abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug (as defined in such part as of such day) that on or after October 1, 2013, but before October 1, 2018, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2019.''

Pub. L. 113–14, title II, § 204, June 13, 2013, 127 Stat. 474, provided that: ''Notwithstanding the amendments made by this title [amending this section and section 379j–22 of this title and repealing provisions set out as notes under this section and section 379j–22 of this title], part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–21 et seq.], as in effect on the day before the date of enactment of this title [June 13, 2013], shall continue to be in effect with respect to abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug (as defined in such part as of such day) that on or after October 1, 2008, but before October 1, 2013, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2014.''

FINDINGS

Pub. L. 118–15, div. B, title III, § 2311(b), Sept. 30, 2023, 137 Stat. 90, provided that: ''Congress finds that the fees authorized by the amendments made in this chapter [chapter 2 (§§ 2311–2316) of subtitle A of title III of div. B of Pub. L. 118–15, amending this section and section 379j–22 of this title and repealing provisions set out as

notes under this section and section 379j–22 of this title] will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified for purposes of part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.''

Similar provisions were contained in the following prior acts:

Pub. L. 115–234, title II, §201(b), Aug. 14, 2018, 132 Stat. 2432.

Pub. L. 113–14, title II, §201(b), June 13, 2013, 127 Stat. 464.

Pub. L. 110–316, title II, §201(b), Aug. 14, 2008, 122 Stat. 3515.

§ 379j–22. Reauthorization; reporting requirements

(a) Performance reports

Beginning with fiscal year 2024, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b)[1] of the Animal Generic Drug User Fee Amendments of 2023 toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs during such fiscal year.

(b) Fiscal report

Beginning with fiscal year 2024, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(c) Public availability

The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) Reauthorization

(1) Consultation

In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of abbreviated applications for generic new animal drugs for the first 5 fiscal years after fiscal year 2028, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) veterinary professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) Prior public input

Prior to beginning negotiations with the regulated industry on the reauthorization of this subpart, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subpart; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) Periodic consultation

Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

(4) Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) Transmittal of recommendations

Not later than January 15, 2028, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

[1] See References in Text note below.