

Subsec. (g)(2)(C)(ii). Pub. L. 115-52, §303(f)(2), substituted “of section 355(j)(5)(A)” for “of 355(j)(5)(A)”.

Subsec. (g)(5). Pub. L. 115-52, §303(f)(3), added par. (5).

Subsec. (h)(2). Pub. L. 115-52, §303(g), struck out “for Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities” after “in the rate.”

Subsec. (i)(2)(A)(i). Pub. L. 115-52, §303(h)(1)(A), substituted “subparagraph (C)” for “subparagraphs (C) and (D)”.

Subsec. (i)(2)(C). Pub. L. 115-52, §303(h)(1)(B), (D), redesignated subpar. (D) as (C) and struck out former subpar. (C). Prior to amendment, text of subpar. (C) read as follows: “Until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.”

Subsec. (i)(2)(D). Pub. L. 115-52, §303(h)(1)(D), redesignated subpar. (D) as (C).

Pub. L. 115-52, §303(h)(1)(C), struck out “in subsequent years” after “payments” in heading and “(after fiscal year 2013)” after “fiscal year” in text.

Subsec. (i)(3). Pub. L. 115-52, §303(h)(2), substituted “fiscal years 2018 through 2022” for “fiscal years 2013 through 2017”.

Subsec. (o). Pub. L. 115-52, §303(i), added subsec. (o).

2012—Subsec. (a). Pub. L. 112-193, §2(b)(2), inserted “for such year” after “obligation of fees” wherever appearing.

Subsec. (i)(2)(C). Pub. L. 112-193, §2(b)(3), inserted comma after “September 30, 2013” and struck out comma after “for fiscal year 2013”.

#### Statutory Notes and Related Subsidiaries

##### EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117-180 effective Oct. 1, 2022, with fees under this subpart to be assessed for all abbreviated new drug applications received on or after Oct. 1, 2022, see section 3005 of Pub. L. 117-180, set out as a note under section 379j-41 of this title.

##### EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by section 303 of Pub. L. 115-52 effective Oct. 1, 2017, with fees under this subpart to be assessed for all abbreviated new drug applications received on or after Oct. 1, 2017, see section 306 of Pub. L. 115-52, set out as a note under section 379j-41 of this title.

##### EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Oct. 1, 2027, see section 3004(a) of Pub. L. 117-180, set out as a note under section 379j-41 of this title.

Section effective Oct. 1, 2012, with fees under this section and section 379j-41 of this title to be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files received on or after Oct. 1, 2012, see section 305 of Pub. L. 112-144, set out as a note under section 379j-41 of this title.

##### FEES AUTHORIZED FOR FISCAL YEAR 2013

Pub. L. 112-193, §2(c), Oct. 5, 2012, 126 Stat. 1443, provided that:

“(1) Notwithstanding section 744B(a)(2)(E)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-42(a)(2)(E)(ii)), the fee authorized under section 744B(a)(2) of such Act for fiscal year 2013 shall be due 30 calendar days after publication of the notice provided for in section 744B(a)(2)(C)(i) of such Act.

“(2) Notwithstanding section 744B(a)(3)(C)(ii) of such Act, the fee authorized under section 744B(a)(3) of such Act for fiscal year 2013 shall be due on the later of—

“(A) the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies; or

“(B) 30 calendar days after publication of the notice referred to in section 744B(a)(3)(B)(i) of such Act.

“(3) Notwithstanding section 744B(a)(4)(D)(i) of such Act, the fee authorized under section 744B(a)(4) of such Act for fiscal year 2013 shall be due not later than 45 days after the publication of the notice under section 744B(a)(4)(C)(i) of such Act.”

#### § 379j-43. Reauthorization; reporting requirements

##### (a) Performance report

###### (1) General requirements

Not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 301(b)<sup>1</sup> of the Generic Drug User Fee Amendments of 2022 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

###### (2) Real time reporting

###### (A) In general

Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this subpart, the Secretary shall post the data described in subparagraph (B) on the internet website of the Food and Drug Administration, and may remove duplicative data from the annual report under this subsection.

###### (B) Data

The Secretary shall post the following data in accordance with subparagraph (A):

(i) The number and titles of draft and final guidance on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b)<sup>1</sup> of the Generic Drug User Fee Amendments of 2022.

(ii) The number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b)<sup>1</sup> of the Generic Drug User Fee Amendments of 2022.

###### (3) Rationale for GDUFA program changes

The Secretary shall include in the annual report under paragraph (1)—

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 379j-42 of this title, and the number of full time equivalents funded by

<sup>1</sup> See References in Text note below.

budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for human generic drug activities, including—

(i) identifying drivers of such changes; and

(ii) changes in the total average cost per full-time equivalent in the generic drug review program;

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required; and

(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of abbreviated new drug application.

#### (4) Analysis

For each fiscal year, the Secretary shall include in the report an analysis of the following:

(A) The difference between the aggregate number of abbreviated new drug applications filed and the aggregate number of approvals or aggregate number of complete response letters issued by the agency, accounting for—

(i) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(ii) the aggregate number of applications for each fiscal year that did not meet the goals identified by the letters described in section 301(b)<sup>1</sup> of the Generic Drug User Fee Amendments of 2022 for the applicable fiscal year.

(B) Relevant data to determine whether the Food and Drug Administration has met the performance enhancement goals identified by the letters described in section 301(b)<sup>1</sup> of the Generic Drug User Fee Amendments of 2022 for the applicable fiscal year.

(C) The most common causes and trends for external or other circumstances that affected the ability of the Secretary to meet review time and performance enhancement goals identified by the letters described in section 301(b)<sup>1</sup> of the Generic Drug User Fee Amendments of 2022.

#### (b) Fiscal report

Not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate 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 for such fiscal year.

#### (c) Corrective action report

For each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate. The report shall include the following information, as applicable:

##### (1) Goals met

For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(4), that each of the goals identified by the letters described in section 301(b)<sup>1</sup> of the Generic Drug User Fee Amendments of 2022 for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the abbreviated new drug application review process.

##### (2) Goals missed

For each of the goals identified by the letters described in section 301(b)<sup>1</sup> of the Generic Drug User Fee Amendments of 2022 for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(A) a detailed justification for such determination and a description, as applicable, of the types of circumstances and trends under which abbreviated new drug applications missed the review goal times but were approved during the first cycle review, or review goals were missed; and

(B) with respect to performance enhancement goals that were not achieved, a detailed description of efforts the Food and Drug Administration has put in place for the fiscal year in which the report is submitted to improve the ability of such agency to meet each such goal for the such<sup>2</sup> fiscal year.

#### (d) Enhanced communication

##### (1) Communications with Congress

Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of human drugs shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

##### (2) Participation in congressional hearing

Each fiscal year, as applicable and requested, representatives from the Food and Drug Administration shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and

<sup>2</sup> So in original.

Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this subpart.

**(e) 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.

**(f) Reauthorization**

**(1) Consultation**

In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year 2027, 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) health care professionals;
- (E) representatives of patient and consumer advocacy groups; and
- (F) the generic drug industry.

**(2) Prior public input**

Prior to beginning negotiations with the generic drug 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 month during negotiations with the generic drug industry, the Secretary shall hold discussions with representatives of 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) Updates to Congress**

The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this part to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

**(5) Public review of recommendations**

After negotiations with the generic drug 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.

**(6) Transmittal of recommendations**

Not later than January 15, 2027, the Secretary shall transmit to the 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.

**(7) Minutes of negotiation meetings**

**(A) Public availability**

The Secretary shall make publicly 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 generic drug industry, not later than 30 days after each such negotiation meeting.

**(B) Content**

The minutes described under subparagraph (A) shall summarize, in sufficient detail, 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, §744C, as added Pub. L. 112-144, title III, §303, July 9, 2012, 126 Stat. 1022; amended Pub. L. 115-52, title III, §304, title IX, §§903(c), 904(c), Aug. 18, 2017, 131 Stat. 1027, 1080, 1085; Pub. L. 117-180, div. F, title III, §3003, Sept. 30, 2022, 136 Stat. 2158; Pub. L. 117-328, div. FF, title III, §3626(c), Dec. 29, 2022, 136 Stat. 5885.)

TERMINATION OF SECTION

*For termination of section by section 3004(b) of Pub. L. 117-180, see Effective and Termination Dates note set out below.*

Editorial Notes

REFERENCES IN TEXT

Section 301(b) of the Generic Drug User Fee Amendments of 2022, referred to in subsecs. (a) and (c), probably should be a reference to section 3001(b) of the Generic Drug User Fee Amendments of 2022, title III of div. F of Pub. L. 117-180, which is set out as a note under section 379j-41 of this title. The Generic Drug User Fee Amendments of 2022 does not contain a section 301(b).

Section 3001(b) of the Generic Drug User Fee Amendments of 2022, referred to in subsec. (a)(3)(A), is section 3001(b) of title III of div. F of Pub. L. 117-180, which is set out as a note under section 379j-41 of this title.

AMENDMENTS

2022—Pub. L. 117-180, §3003(2), substituted “Generic Drug User Fee Amendments of 2022” for “Generic Drug User Fee Amendments of 2017” wherever appearing.

Subsec. (a)(1). Pub. L. 117-180, §3003(1), substituted “Not later” for “Beginning with fiscal year 2018, not later”.

Subsec. (a)(2). Pub. L. 117-180, §3003(3), substituted “Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this subpart” for “Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter”.

Subsec. (a)(3). Pub. L. 117-180, §3003(4), substituted “The Secretary” for “Beginning with fiscal year 2020, the Secretary” in introductory provisions.

Subsec. (a)(3)(A). Pub. L. 117-328, §3626(c)(1)(A), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: “data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022 and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;”.

Subsec. (a)(3)(B). Pub. L. 117-328, §3626(c)(1)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “data, analysis, and discussion of the changes in the fee revenue amounts and costs for human generic drug activities, including identifying drivers of such changes; and”.

Subsec. (a)(3)(D). Pub. L. 117-328, §3626(c)(1)(C), (D), added subpar. (D).

Subsec. (b). Pub. L. 117-180, §3003(5), substituted “Not later” for “Beginning with fiscal year 2018, not later”.

Subsec. (c). Pub. L. 117-180, §3003(6), substituted “For each” for “Beginning with fiscal year 2018, for each” in introductory provisions.

Subsec. (f)(1). Pub. L. 117-180, §3003(7)(A), substituted “fiscal year 2027” for “fiscal year 2022” in introductory provisions.

Subsec. (f)(4). Pub. L. 117-328, §3626(c)(2)(B), added par. (4). Former par. (4) redesignated (5).

Subsec. (f)(5). Pub. L. 117-328, §3626(c)(2)(A), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Pub. L. 117-180, §3003(7)(B), substituted “January 15, 2027” for “January 15, 2022”.

Subsec. (f)(6), (7). Pub. L. 117-328, §3626(c)(2)(A), redesignated pars. (5) and (6) as (6) and (7), respectively.

Subsec. (f)(7)(A). Pub. L. 117-328, §3626(c)(2)(C)(i), substituted “The” for “Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the” and inserted “, not later than 30 days after each such negotiation meeting” before period at end.

Subsec. (f)(7)(B). Pub. L. 117-328, §3626(c)(2)(C)(ii), inserted “, in sufficient detail,” after “shall summarize”.

2017—Subsec. (a). Pub. L. 115-52, §903(c), designated existing provisions as par. (1), inserted heading, and added pars. (2) and (3).

Pub. L. 115-52, §304(1), substituted “2018” for “2013” and “Generic Drug User Fee Amendments of 2017” for “Generic Drug User Fee Amendments of 2012”.

Subsec. (a)(4). Pub. L. 115-52, §904(c)(1), added par. (4).

Subsec. (b). Pub. L. 115-52, §304(2), substituted “2018” for “2013”.

Subsecs. (c) to (e). Pub. L. 115-52, §904(c)(2), added subsecs. (c) and (d) and redesignated former subsec. (c) as (e). Former subsec. (d) redesignated (f).

Subsec. (f). Pub. L. 115-52, §904(c)(2)(A), redesignated subsec. (d) as (f).

Pub. L. 115-52, §304(3), which directed amendment of subsec. (d), effective Oct. 1, 2017, by substituting “2022” for “2017” wherever appearing, was executed by making the substitution in subsec. (f) to reflect the probable intent of Congress and the redesignation of subsec. (d) as (f), effective Aug. 18, 2017, by Pub. L. 115-52, §904(c)(2). See Amendment note above.

## Statutory Notes and Related Subsidiaries

### EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117-180 effective Oct. 1, 2022, with fees under this subpart to be assessed for all abbreviated new drug applications received on or after Oct. 1, 2022, see section 3005 of Pub. L. 117-180, set out as a note under section 379j-41 of this title.

### EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by section 304 of Pub. L. 115-52 effective Oct. 1, 2017, with fees under this subpart to be assessed for all abbreviated new drug applications received on or after Oct. 1, 2017, see section 306 of Pub. L. 115-52, set out as a note under section 379j-41 of this title.

### EFFECTIVE AND TERMINATION DATES

Pub. L. 117-180, div. F, title III, §3004(b), Sept. 30, 2022, 136 Stat. 2159, provided that: “Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-43) shall cease to be effective January 31, 2028.”

Pub. L. 115-52, title III, §305(b), Aug. 18, 2017, 131 Stat. 1027, which provided that this section would cease to be effective Jan. 31, 2023, was repealed by Pub. L. 117-180, div. F, title III, §3004(c), Sept. 30, 2022, 136 Stat. 2159.

[Pub. L. 117-180, div. F, title III, §3004(c), Sept. 30, 2022, 136 Stat. 2159, provided that the repeal of section 305(b) of Pub. L. 115-52, formerly set out above, is effective Oct. 1, 2022.]

Pub. L. 112-144, title III, §304(b), July 9, 2012, 126 Stat. 1024, which provided that this section would cease to be effective Jan. 31, 2018, was repealed by Pub. L. 115-52, title III, §305(c)(1), Aug. 18, 2017, 131 Stat. 1027.

[Pub. L. 115-52, title III, §305(c)(1), Aug. 18, 2017, 131 Stat. 1027, provided that the repeal of section 304(b) of Pub. L. 112-144, formerly set out above, is effective Oct. 1, 2017.]

Section effective Oct. 1, 2012, see section 305 of Pub. L. 112-144, set out as a note under section 379j-41 of this title.

### SUBPART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

## § 379j-51. Definitions

For purposes of this subpart:

(1) The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All items) for September of the preceding fiscal year divided by such Index for September 2011.

(2) The term “affiliate” means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(3) The term “biosimilar biological product” means a specific strength of a biological product in final dosage form for which a biosimilar biological product application has been approved.

(4)(A) Subject to subparagraph (B), the term “biosimilar biological product application” means an application for licensure of a biological product under section 262(k) of title 42.

(B) Such term does not include—

(i) a supplement to such an application;

(ii) an application filed under section 262(k) of title 42 that cites as the reference