ably should be a reference to section 4001(b) of the Biosimilar User Fee Amendments of 2022, title IV of div. F of Pub. L. 117–180, which is set out as a note under section 379j–51 of this title. The Biosimilar User Fee Amendments of 2022 does not contain a section 401(b).

Section 4001(b) of the Biosimilar User Fee Amendments of 2022, referred to in subsec. (a)(4)(A), is section 4001(b) of title IV of div. F of Pub. L. 117–180, which is set out as a note under section 379j–51 of this title.

CODIFICATION

Amendments made by section 904(d)(2) of Pub. L. 115–52, effective Aug. 18, 2017, were executed after the amendments made by section 404(3)–(5) of Pub. L. 115–52, effective Oct. 1, 2017, to reflect the probable intent of Congress and the directory language of section 904(d)(2) of Pub. L. 115–52, which expressly amended this section ''as amended by section 404'' of Pub. L. 115–52. See 2017 Amendment notes below.

AMENDMENTS

2022—Pub. L. 117–180, § 4004(2), substituted ''Biosimilar User Fee Amendments of 2022'' for ''Biosimilar User Fee Amendments of 2017'' wherever appearing.

Subsec. (a)(1). Pub. L. 117–180, § 4004(1), substituted ''Not'' for ''Beginning with fiscal year 2018, not''.

Subsec. (a)(2). Pub. L. 117–180, § 4004(3), substituted ''The'' for ''Beginning with fiscal year 2018, the'' in introductory provisions.

Subsec. (a)(3)(A). Pub. L. 117–180, § 4004(4), 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)(4)(A). Pub. L. 117–328, § 3626(d)(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 401(b) of the Biosimilar 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)(4)(B). Pub. L. 117–328, § 3626(d)(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 the process for the review of biosimilar biological product applications, including identifying drivers of such changes; and''.

Subsec. (a)(4)(D). Pub. L. 117–328, § 3626(d)(1)(C), (D), added subpar. (D).

Subsec. (b). Pub. L. 117–180, § 4004(5), substituted ''Not later than 120 days after the end of each fiscal year for which fees are collected under this subpart'' for ''Not later than 120 days after the end of fiscal year 2018 and each subsequent fiscal year for which fees are collected under this subpart''.

Subsec. (c). Pub. L. 117–180, § 4004(6), substituted ''For'' for ''Beginning with fiscal year 2018, and for'' in introductory provisions.

Subsec. (f)(1). Pub. L. 117–180, § 4004(7)(A), substituted ''fiscal year 2027'' for ''fiscal year 2022'' in introductory provisions.

Subsec. (f)(2). Pub. L. 117–328, § 3626(d)(2)(B), added par. (2). Former par. (2) redesignated (5).

Subsec. (f)(3). Pub. L. 117–328, § 3626(d)(2)(B), added par. (3). Former par. (3) redesignated (6).

Pub. L. 117–180, § 4004(7)(B), substituted ''January 15, 2027'' for ''January 15, 2022''.

Subsec. (f)(4) to (7). Pub. L. 117–328, § 3626(d)(2), added pars. (4) and (7) and redesignated formers pars. (2) and (3) as (5) and (6), respectively.

2017—Subsec. (a). Pub. L. 115–52, § 903(d), designated existing provisions as par. (1), inserted heading, and added pars. (2) to (4).

Pub. L. 115–52, § 404(1), substituted ''2018'' for ''2013'' and ''Biosimilar User Fee Amendments of 2017'' for ''Biosimilar User Fee Act of 2012''.

Subsec. (a)(5). Pub. L. 115–52, § 904(d)(1), added par. (5).

Subsec. (b). Pub. L. 115–52, § 404(2), substituted ''2018'' for ''2013''.

Subsec. (c). Pub. L. 115–52, § 904(d)(2), added subsec. (c). Former subsec. (c) redesignated (e).

Subsecs. (d), (e). Pub. L. 115–52, § 904(d)(2), added subsec. (d) and redesignated subsec. (c) as (e). Former subsec. (d), as redesignated by section 404(4) of Pub. L. 115–52, redesignated (f). See Amendment notes below.

Pub. L. 115–52, § 404(3)–(5), redesignated subsec. (e) as (d), substituted ''2022'' for ''2017'' in pars. (1) and (3), and struck out former subsec. (d) which related to a study of the workload volume and full costs associated with the process for the review of biosimilar biological product applications.

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

**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 biosimilar biological product applications received on or after Oct. 1, 2022, see section 4006 of Pub. L. 117–180, set out as a note under section 379j–51 of this title.

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by section 404 of Pub. L. 115–52 effective Oct. 1, 2017, with fees under this subpart to be assessed for all biosimilar biological product applications received on or after Oct. 1, 2017, see section 406 of Pub. L. 115–52, set out as a note under section 379j–51 of this title.

EFFECTIVE AND TERMINATION DATES

Pub. L. 117–180, div. F, title IV, § 4005(b), Sept. 30, 2022, 136 Stat. 2166, provided that: ''Section 744I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53) shall cease to be effective January 31, 2028.''

Pub. L. 115–52, title IV, § 405(b), Aug. 18, 2017, 131 Stat. 1035, which provided that this section would cease to be effective Jan. 31, 2023, was repealed by Pub. L. 117–180, div. F, title IV, § 4005(c), Sept. 30, 2022, 136 Stat. 2166.

[Pub. L. 117–180, div. F, title IV, § 4005(c), Sept. 30, 2022, 136 Stat. 2166, provided that the repeal of section 405(b) of Pub. L. 115–52, formerly set out above, is effective Oct. 1, 2022.]

Pub. L. 112–144, title IV, § 404(b), July 9, 2012, 126 Stat. 1038, which provided that this section would cease to be effective Jan. 31, 2018, was repealed by Pub. L. 115–52, title IV, § 405(c)(1), Aug. 18, 2017, 131 Stat. 1035.

[Pub. L. 115–52, title III, § 405(c)(1), Aug. 18, 2017, 131 Stat. 1035, provided that the repeal of section 404(b) of Pub. L. 112–144, formerly set out above, is effective Oct. 1, 2017.]

Section effective Oct. 1, 2012, see section 405 of Pub. L. 112–144, set out as a note under section 379j–51 of this title.

## SUBPART 9—FEES RELATING TO OUTSOURCING FACILITIES

### § 379j–61. Definitions

In this subpart:

(1) The term ''affiliate'' has the meaning given such term in section 379g(11) of this title.

(2) The term ''gross annual sales'' means the total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all the affiliates of the outsourcing facility.

(3) The term ''outsourcing facility'' has the meaning given to such term in section 353b(d)(4) of this title.

(4) The term ''reinspection'' means, with respect to an outsourcing facility, 1 or more inspections conducted under section 374 of this title subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this chapter, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.

(June 25, 1938, ch. 675, § 744J, as added Pub. L. 113–54, title I, § 102(b), Nov. 27, 2013, 127 Stat. 593.)

### § 379j–62. Authority to assess and use outsourcing facility fees

**(a) Establishment and reinspection fees**

**(1) In general**

For fiscal year 2015 and each subsequent fiscal year, the Secretary shall, in accordance with this subsection, assess and collect—

(A) an annual establishment fee from each outsourcing facility; and

(B) a reinspection fee from each outsourcing facility subject to a reinspection in such fiscal year.

**(2) Multiple reinspections**

An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

**(b) Establishment and reinspection fee setting**

The Secretary shall—

(1) establish the amount of the establishment fee and reinspection fee to be collected under this section for each fiscal year based on the methodology described in subsection (c); and

(2) publish such fee amounts in a Federal Register notice not later than 60 calendar days before the start of each such year.

**(c) Amount of establishment fee and reinspection fee**

**(1) In general**

For each outsourcing facility in a fiscal year—

(A) except as provided in paragraph (4), the amount of the annual establishment fee under subsection (b) shall be equal to the sum of—

(i) $15,000, multiplied by the inflation adjustment factor described in paragraph (2); plus

(ii) the small business adjustment factor described in paragraph (3); and

(B) the amount of any reinspection fee (if applicable) under subsection (b) shall be equal to $15,000, multiplied by the inflation adjustment factor described in paragraph (2).

**(2) Inflation adjustment factor**

**(A) In general**

For fiscal year 2015 and subsequent fiscal years, the fee amounts established in paragraph (1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

(i) 1;

(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 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years; plus

(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years.

**(B) Compounded basis**

The adjustment made each fiscal year under subparagraph (A) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under subparagraph (A).

**(3) Small business adjustment factor**

The small business adjustment factor described in this paragraph shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

(A) the number of small businesses that will pay a reduced establishment fee for such fiscal year; and

(B) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in paragraph (4).

**(4) Exception for small businesses**

**(A) In general**

In the case of an outsourcing facility with gross annual sales of $1,000,000 or less in the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this section are assessed, the amount of the establishment fee under subsection (b) for a fiscal year shall be equal to \1/3\ of the amount calculated under paragraph (1)(A)(i) for such fiscal year.

**(B) Application**

To qualify for the exception under this paragraph, a small business shall submit to the Secretary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application shall be submitted to the Secretary not later than April 30 of such immediately preceding fiscal year.

**(5) Crediting of fees**

In establishing the small business adjustment factor under paragraph (3) for a fiscal year, the Secretary shall—