

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)<sup>1</sup> 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.

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

**(6) Minutes of negotiation meetings****(A) Public availability**

Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, 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 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, §742, as added Pub. L. 110-316, title II, §203, Aug. 14, 2008, 122 Stat. 3522; amended Pub. L. 113-14, title II, §203, June 13, 2013, 127 Stat. 472; Pub. L. 115-234, title II, §203, Aug. 14, 2018, 132 Stat. 2435; Pub. L. 118-15, div. B, title III, §2313, Sept. 30, 2023, 137 Stat. 93.)

**TERMINATION OF SECTION**

*For termination of section by section 2316(b) of Pub. L. 118-15, see Termination Date note below.*

**Editorial Notes****REFERENCES IN TEXT**

Section 201(b) of the Animal Generic Drug User Fee Amendments of 2023, referred to in subsec. (a), probably should be a reference to section 2311(b) of the Animal Generic Drug User Fee Amendments of 2023, chapter 2 of subtitle A of title III of div. B of Pub. L. 118-15, which is set out as a note under section 379j-21 of this title. The Animal Generic Drug User Fee Amendments of 2023 does not contain a section 201(b).

**PRIOR PROVISIONS**

A prior section 742 of act June 25, 1938, was renumbered section 746 and is classified to section 379l of this title.

**AMENDMENTS**

2023—Subsec. (a). Pub. L. 118-15, §2313(1), (2), substituted “2024” for “2019” and “2023” for “2018”.

Subsec. (b). Pub. L. 118-15, §2313(2), substituted “2024” for “2019”.

Subsec. (d)(1), (5). Pub. L. 118-15, §2313(3), substituted “2028” for “2023”.

2018—Subsec. (a). Pub. L. 115-234, §203(1), (3), substituted “2019” for “2014” and “2018” for “2013”.

Subsec. (b). Pub. L. 115-234, §203(2), (3), substituted “2019” for “2014” and “to the Committee on Health, Education, Labor and Pensions” for “to Committee on Health, Education, Labor, and Pensions”.

Subsec. (d)(1), (5). Pub. L. 115-234, §203(4), 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 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, to 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 Oct. 1, 2023, see section 2315 of Pub. L. 118-15, set out as a note under section 379j-21 of this title.

**EFFECTIVE DATE OF 2018 AMENDMENT**

Amendment by Pub. L. 115-234 effective on Oct. 1, 2018, and 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, to 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 Oct. 1, 2018, see section 205 of Pub. L. 115-234, set out as a note under section 379j-21 of this title.

**EFFECTIVE DATE OF 2013 AMENDMENT**

Amendment by Pub. L. 113-14 effective Oct. 1, 2013, see section 205 of Pub. L. 113-14, set out as a note under section 379j-21 of this title.

**TERMINATION DATE**

Pub. L. 118-15, div. B, title III, §2316(b), Sept. 30, 2023, 137 Stat. 94, provided that: “Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-22) shall cease to be effective January 31, 2029.”

Pub. L. 115-234, title II, §206(b), Aug. 14, 2018, 132 Stat. 2435, which provided that section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-22) would cease to be effective Jan. 31, 2024, 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(b), June 13, 2013, 127 Stat. 474, which provided that section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-22) would cease to be effective Jan. 31, 2019, 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(b), Aug. 14, 2008, 122 Stat. 3524, which provided that the amendment made by section 203 of Pub. L. 110-316 (enacting this section) would cease to be effective Jan. 31, 2014, was repealed by Pub. L. 113-14, title II, §206(c)(1), June 13, 2013, 127 Stat. 474.

**SUBPART 6—FEES RELATED TO FOOD****§ 379j-31. Authority to collect and use fees****(a) In general****(1) Purpose and authority**

For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, in accordance with this section, assess and collect fees from—

(A) the responsible party for each domestic facility (as defined in section 350d(b)<sup>1</sup> of this title) and the United States agent for each foreign facility subject to a reinspection in such fiscal year, to cover reinspection-related costs for such year;

(B) the responsible party for a domestic facility (as defined in section 350d(b)<sup>1</sup> of this title) and an importer who does not comply with a recall order under section 350l of this title or under section 350a(f) of this title in such fiscal year, to cover food recall activities associated with such order performed by the Secretary, including technical assistance, follow-up effectiveness checks, and public notifications, for such year;

(C) each importer participating in the voluntary qualified importer program under section 384b of this title in such year, to

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