

tion or supplemental abbreviated application, but not after such application has been approved.

(11) 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.)

TERMINATION OF SECTION

For termination of section by section 204(a) of Pub. L. 110–316, see Termination Date note below.

PRIOR PROVISIONS

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

TERMINATION DATE

Pub. L. 110–316, title II, §204(a), Aug. 14, 2008, 122 Stat. 3524, provided that: “The amendments made by section 202 [enacting this section and amending sections 379k, 379l, and 379o of this title] shall cease to be effective October 1, 2013.”

FINDINGS

Pub. L. 110–316, title II, §201(b), Aug. 14, 2008, 122 Stat. 3515, provided that: “Congress finds as follows:

“(1) Prompt approval of abbreviated applications for safe and effective generic new animal drugs will reduce animal healthcare costs and promote the well-being of animal health and the public health.

“(2) Animal health and the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for the review of abbreviated applications for the approval of generic new animal drugs.

“(3) The fees authorized by this title [see Short Title of 2008 Amendment note set out under section 301 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 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.”

§ 379j–22. Reauthorization; reporting requirements

(a) Performance reports

Beginning with fiscal year 2009, not later than 60 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 sec-

tion 201(3)¹ of the Animal Generic Drug User Fee Act of 2008 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 2009, 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 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 2013, 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

¹ See References in Text note below.

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, 2013, 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.

(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.)

TERMINATION OF SECTION

For termination of section by section 204(b) of Pub. L. 110-316, see Termination Date note below.

REFERENCES IN TEXT

Section 201(3) of the Animal Generic Drug User Fee Act of 2008, referred to in subsec. (a), probably means section 201(b)(3) of Pub. L. 110-316, which is set out as a note under section 379j-21 of this title.

PRIOR PROVISIONS

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

TERMINATION DATE

Pub. L. 110-316, title II, §204(b), Aug. 14, 2008, 122 Stat. 3524, provided that: “The amendment made by section

203 [enacting this section] shall cease to be effective January 31, 2014.”

PART D—INFORMATION AND EDUCATION

§ 379k. Information system

The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.

(June 25, 1938, ch. 675, §745, formerly §741, as added Pub. L. 105-115, title IV, §407(a), Nov. 21, 1997, 111 Stat. 2370; renumbered §745, Pub. L. 110-316, title II, §202(a), Aug. 14, 2008, 122 Stat. 3515.)

AMENDMENT OF SECTION

For termination of amendment renumbering this section by section 204(a) of Pub. L. 110-316, see Termination Date of 2008 Amendment note below.

TERMINATION DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110-316 to cease to be effective Oct. 1, 2013, see section 204(a) of Pub. L. 110-316, set out as a Termination Date note under section 379j-21 of this title.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

REPORT ON STATUS OF SYSTEM

Section 407(b) of Pub. L. 105-115 provided that not later than 1 year after Nov. 21, 1997, Secretary of Health and Human Services was to submit report to Congress on status of system to be established under this section, including projected costs of system and concerns about confidentiality.

§ 379l. Education

(a) In general

The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this chapter, including programs for—

(1) scientific training;

(2) training to improve the skill of officers and employees authorized to conduct inspections under section 374 of this title;

(3) training to achieve product specialization in such inspections; and

(4) training in administrative process and procedure and integrity issues.

(b) Intramural fellowships and other training programs

The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians. Any such fellowships and training programs under this section or under section 379dd(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary deter-