

TERMINATION OF SECTION

For termination of section by section 106(a) of Pub. L. 110-85, see Effective and Termination Dates note below.

EFFECTIVE AND TERMINATION DATES

Section effective Oct. 1, 2007, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2007, and ceases to be effective Oct. 1, 2012, see sections 106(a) and 107 of Pub. L. 110-85, set out as Effective and Termination Dates of 2007 Amendment notes under section 379g of this title.

§ 379h-2. Reauthorization; reporting requirements

(a) Performance report

Beginning with fiscal year 2008, 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 101(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

(b) Fiscal report

Beginning with fiscal year 2008, 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) 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 the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, 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 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 month during negotiations with the regulated 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) 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, 2012, 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.

(6) Minutes of negotiation meetings

(A) Public availability

Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public 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 pro-

posals 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, §736B, as added Pub. L. 110-85, title I, §105, Sept. 27, 2007, 121 Stat. 840.)

TERMINATION OF SECTION

For termination of section by section 106(b) of Pub. L. 110-85, see Effective and Termination Dates note below.

REFERENCES IN TEXT

Section 101(c) of the Food and Drug Administration Amendments Act of 2007, referred to in subsec. (a), is section 101(c) of Pub. L. 110-85, which is set out as a note under section 379g of this title.

EFFECTIVE AND TERMINATION DATES

Pub. L. 110-85, title I, §106(b), Sept. 27, 2007, 121 Stat. 842, provided that: "The amendment made by section 105 [enacting this section] ceases to be effective January 31, 2013."

Section effective Oct. 1, 2007, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2007, see section 107 of Pub. L. 110-85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379g of this title.

SUBPART 3—FEES RELATING TO DEVICES

TERMINATION OF SUBPART

For termination of subpart by section 107 of Pub. L. 107-250, see Effective and Termination Dates note set out under section 379i of this title.

§ 379i. Definitions

For purposes of this subpart:

(1) The term "premarket application" means—

(A) an application for approval of a device submitted under section 360e(c) of this title or section 262 of title 42; or

(B) a product development protocol described in section 360e(f) of this title.

Such term does not include a supplement, a premarket report, or a premarket notification submission.

(2) The term "premarket report" means a report submitted under section 360e(c)(2) of this title.

(3) The term "premarket notification submission" means a report submitted under section 360(k) of this title.

(4)(A) The term "supplement", with respect to a panel-track supplement, a 180-day supplement, a real-time supplement, or an efficacy supplement, means a request to the Secretary to approve a change in a device for which—

(i) an application or report has been approved under section 360e(d) of this title, or an application has been approved under section 262 of title 42; or

(ii) a notice of completion has become effective under section 360e(f) of this title.

(B) The term "panel-track supplement" means a supplement to an approved premarket application or premarket report under section 360e of this title that requests a significant change in design or performance of the device,

or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

(C) The term "180-day supplement" means a supplement to an approved premarket application or premarket report under section 360e of this title that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.

(D) The term "real-time supplement" means a supplement to an approved premarket application or premarket report under section 360e of this title that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

(E) The term "efficacy supplement" means a supplement to an approved premarket application under section 262 of title 42 that requires substantive clinical data.

(5) The term "30-day notice" means a notice under section 360e(d)(6) of this title that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

(6) The term "request for classification information" means a request made under section 360e(g) of this title for information respecting the class in which a device has been classified or the requirements applicable to a device.

(7) The term "annual fee", for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.

(8) The term "process for the review of device applications" means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions:

(A) The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(B) The issuance of action letters that allow the marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, premarket reports, and supplements.

(D) Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions.

(E) Review of device applications subject to section 262 of title 42 for an investigational new drug application under section