(11) The term ''submission for advisory review'' means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.

(June 25, 1938, ch. 675, § 736A, as added Pub. L. 110–85, title I, § 104, Sept. 27, 2007, 121 Stat. 832.)

EFFECTIVE DATE

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.

§ 379h–2. Reauthorization; reporting requirements

(a) Performance report

(1) In general

Beginning with fiscal year 2013, 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—

(A) the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals, including the status of the independent assessment described in such letters; and

(B) the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including, for each review division—

(i) the number of original standard new drug applications and biologics license applications filed per fiscal year for each review division;

(ii) the number of original priority new drug applications and biologics license applications filed per fiscal year for each review division;

(iii) the number of standard efficacy supplements filed per fiscal year for each review division;

(iv) the number of priority efficacy supplements filed per fiscal year for each review division;

(v) the number of applications filed for review under accelerated approval per fiscal year for each review division;

(vi) the number of applications filed for review as fast track products per fiscal year for each review division;

(vii) the number of applications filed for orphan-designated products per fiscal year for each review division; and

(viii) the number of breakthrough designations for a fiscal year for each review division.

(2) Inclusion

The report under this subsection 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 2013, 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 2017, 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, 2017, 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 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, §736B, as added Pub. L. 110–85, title I, §105, Sept. 27, 2007, 121 Stat. 840; amended Pub. L. 112–144, title I, §104, July 9, 2012, 126 Stat. 1000.)

TERMINATION OF SECTION

For termination of section by section 105(b) of Pub. L. 112–144, see Effective and Termination Dates note below.

REFERENCES IN TEXT

Section 101(b) of the Prescription Drug User Fee Amendments of 2012, referred to in subsec. (a)(1)(A), is section 101(b) of Pub. L. 112–144, which is set out as a note under section 379g of this title.

AMENDMENTS

2012—Subsec. (a). Pub. L. 112–144, §104(1), amended subsec. (a) generally. Prior to amendment, text read as follows: ''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.''

Subsec. (b). Pub. L. 112–144, §104(2), substituted ''2013'' for ''2008''.

Subsec. (d)(1), (5). Pub. L. 112–144, §104(3), substituted ''2017'' for ''2012''.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–144 effective Oct. 1, 2012, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2012, see section 106 of Pub. L. 112–144, set out as a note under section 379g of this title.

EFFECTIVE AND TERMINATION DATES

Pub. L. 112–144, title I, §105(b), July 9, 2012, 126 Stat. 1001, provided that: ''Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) shall cease to be effective January 31, 2018.''

Pub. L. 110–85, title I, §106(b), Sept. 27, 2007, 121 Stat. 842, which provided that the amendment made by section 105 of Pub. L. 110–85 (enacting this section) would cease to be effective Jan. 31, 2013, was repealed by Pub. L. 112–144, title I, §105(c)(1), July 9, 2012, 126 Stat. 1001.

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

§ 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.