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 360c(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 355(i) of this title or for an investigational device exemption under section 360j(g) of this title and activities conducted in anticipation of the submission of such applications under section 355(i) or 360j(g) of this title.

(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 360d of this title in connection with the review of such applications, reports, supplements, or submissions and related activities.

(H) The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.

(I) Any activity undertaken under section 360c or 360e(i) of this title in connection with the initial classification or reclassification of a device or under section 360e(b) of this title in connection with any requirement for approval of a device.

(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 360e of this title or a premarket application under section 262 of title 42.

(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions.

(9) The term ''costs of resources allocated for the process for the review of device applications'' means the expenses incurred in connection with the process for the review of device applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions.

(10) The term ''adjustment factor'' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2001.

(11) The term ''person'' includes an affiliate thereof.

(12) The term ''affiliate'' means a business entity that has a relationship with a second business entity (whether domestic or international) if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(13) The term ''establishment subject to a registration fee'' means an establishment that is required to register with the Secretary under section 360 of this title and is one of the following types of establishments:

(A) Manufacturer

An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

(B) Single-use device reprocessor

An establishment that, within the meaning of section 321(*ll*)(2)(A) of this title, performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.

(C) Specification developer

An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

(June 25, 1938, ch. 675, § 737, as added Pub. L. 107–250, title I, § 102(a), Oct. 26, 2002, 116 Stat. 1589; amended Pub. L. 108–214, § 2(a)(1), (d)(3)(A), Apr. 1, 2004, 118 Stat. 572, 577; Pub. L. 110–85, title II, § 211, Sept. 27, 2007, 121 Stat. 843.)

AMENDMENT OF SECTION

For termination of amendment by section 217 of Pub. L. 110–85, see Effective and Termination Dates of 2007 Amendment note below.

TERMINATION OF SECTION

For termination of section by section 107 of Pub. L. 107–250, see Effective and Termination Dates note set out below.

AMENDMENTS

2007—Pub. L. 110–85, §§ 211(1), 217, temporarily substituted ''For purposes of this subpart'' for ''For purposes of this part'' in introductory provisions. See Effective and Termination Dates of 2007 Amendment note below.

Pars. (5) to (9). Pub. L. 110–85, §§ 211(2), (3), 217, temporarily added pars. (5) to (7) and redesignated former pars. (5) and (6) as (8) and (9), respectively. Former pars. (7) and (8) redesignated (10) and (12), respectively. See Effective and Termination Dates of 2007 Amendment note below.

Par. (10). Pub. L. 110–85, §§ 211(2), (4), 217, temporarily redesignated par. (7) as (10) and substituted ''October of the preceding fiscal year'' for ''April of the preceding fiscal year'' and ''October 2001'' for ''April 2002''. See Effective and Termination Dates of 2007 Amendment note below.

Par. (11). Pub. L. 110–85, §§ 211(5), 217, temporarily added par. (11). See Effective and Termination Dates of 2007 Amendment note below.

Par. (12). Pub. L. 110–85, §§ 211(2), 217, temporarily redesignated par. (8) as (12). See Effective and Termination Dates of 2007 Amendment note below.

Par. (13). Pub. L. 110–85, §§ 211(6), 217, temporarily added par. (13). See Effective and Termination Dates of 2007 Amendment note below.

2004—Pub. L. 108–214, § 2(d)(3)(A), made technical correction to directory language of Pub. L. 107–250, § 102(a), which enacted this section.

Par. (4)(B). Pub. L. 108–214, § 2(a)(1)(A), substituted ''and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness'' for ''and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness''.

Par. (4)(D). Pub. L. 108–214, § 2(a)(1)(B), struck out ''manufacturing,'' after ''software,''.

Par. (5)(J). Pub. L. 108–214, § 2(a)(1)(C), substituted ''a premarket application or premarket report under section 360e of this title or a premarket application under section 262 of title 42.'' for ''a premarket application under section 360e of this title or section 262 of title 42.''

Par. (8). Pub. L. 108–214, § 2(a)(1)(D), substituted ''The term 'affiliate' means a business entity that has a relationship with a second business entity (whether domestic or international)'' for ''The term 'affiliate' means a business entity that has a relationship with a second business entity''.

EFFECTIVE AND TERMINATION DATES OF 2007 AMENDMENT

Pub. L. 110–85, title II, § 216, Sept. 27, 2007, 121 Stat. 852, provided that: ''The amendments made by this subtitle [subtitle A (§§ 211–217) of title II of Pub. L. 110–85,

enacting section 379j–1 of this title and amending this section and section 379j of this title] shall take effect on October 1, 2007, or the date of the enactment of this Act [Sept. 27, 2007], whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart] shall be assessed for all premarket applications, premarket reports, supplements, 30-day notices, and premarket notification submissions received on or after October 1, 2007, regardless of the date of the enactment of this Act.''

Pub. L. 110–85, title II, § 217, Sept. 27, 2007, 121 Stat. 852, provided that: ''The amendments made by this subtitle [subtitle A (§§ 211–217) of title II of Pub. L. 110–85, enacting section 379j–1 of this title and amending this section and section 379j of this title] cease to be effective October 1, 2012, except that section 738A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–1] (regarding annual performance and financial reports) ceases to be effective January 31, 2013.''

EFFECTIVE AND TERMINATION DATES

Pub. L. 107–250, title I, § 106, Oct. 26, 2002, 116 Stat. 1602, provided that: ''The amendments made by this title [enacting this subpart] shall take effect on the date of the enactment of this Act [Oct. 26, 2002], except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notification submissions received on or after October 1, 2002, regardless of the date of enactment.''

Pub. L. 107–250, title I, § 107, Oct. 26, 2002, 116 Stat. 1602, provided that: ''The amendments made by this title [enacting this subpart] cease to be effective October 1, 2007, except that section 103 [set out as a note below] with respect to annual reports ceases to be effective January 31, 2008.''

SAVINGS PROVISION

Pub. L. 110–85, title II, § 214, Sept. 27, 2007, 121 Stat. 852, provided that: ''Notwithstanding section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) [set out as an Effective and Termination Dates note above], and notwithstanding the amendments made by this subtitle [subtitle A (§§ 211–217) of title II of Pub. L. 110–85, enacting section 379j–1 of this title and amending this section and section 379j of this title], part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this subtitle [Sept. 27, 2007], shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.''

FINDINGS

Pub. L. 110–85, title II, § 201(c), Sept. 27, 2007, 121 Stat. 842, provided that: ''The Congress finds that the fees authorized under the amendments made by this title [enacting section 379j–1 of this title and amending this section and sections 333, 360, 360i, 360m, 374, and 379j of this title] will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart] in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.''

Pub. L. 107–250, title I, § 101, Oct. 26, 2002, 116 Stat. 1589, provided that: ''The Congress finds that—

''(1) prompt approval and clearance of safe and effective devices is critical to the improvement of the public health so that patients may enjoy the benefits of devices to diagnose, treat, and prevent disease;

''(2) 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 devices and the assurance of device safety and effectiveness so that statutorily mandated deadlines may be met; and

''(3) the fees authorized by this title [enacting this subpart and provisions set out as notes under this section and section 379j of this title] will be dedicated to meeting the goals identified in the letters from the Secretary of Health and Human Services to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, as set forth in the Congressional Record.''

ANNUAL REPORTS

Pub. L. 107–250, title I, § 103, Oct. 26, 2002, 116 Stat. 1600, as amended by Pub. L. 109–43, § 2(b), Aug. 1, 2005, 119 Stat. 441, which directed the Secretary of Health and Human Services to submit annual reports to Congress on progress in achieving goals identified in section 101(3), set out above, and implementation of authority for and use of fees collected under the medical device user-fee program established under this subpart, ceased to be effective Jan. 31, 2008. See Effective and Termination Dates note above.

STUDY

Pub. L. 107–250, title I, § 104(b), Oct. 26, 2002, 116 Stat. 1601, directed the Secretary of Health and Human Services to conduct a study for the purpose of making certain determinations regarding the medical device user-fee program established under the amendment made by section 102 of Pub. L. 107–250 and to submit a report to Congress by Jan. 10, 2007.

CONSULTATION

Pub. L. 107–250, title I, § 105, Oct. 26, 2002, 116 Stat. 1601, provided that:

''(a) IN GENERAL.—In developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of medical device applications for fiscal years after fiscal year 2007, and for the reauthorization of sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379i, 379j], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry.

''(b) RECOMMENDATIONS.—The Secretary shall publish in the Federal Register recommendations under subsection (a), after negotiations with the regulated industry; shall present such recommendations to the congressional committees specified in such paragraph; shall hold a meeting at which the public may present its views on such recommendations; and shall provide for a period of 30 days for the public to provide written comments on such recommendations.''

§ 379j. Authority to assess and use device fees

(a) Types of fees

(1) In general

Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section.