

Subsec. (c)(4). Pub. L. 109-43, §2(a)(2)(B), struck out par. (4) which provided for a fiscal year 2007 adjustment of the fee revenues established in subsec. (b) to provide for operating reserves of carryover user fees.

Subsec. (c)(5), (6). Pub. L. 109-43, §2(a)(2)(C), redesignated pars. (5) and (6) as (1) and (2), respectively.

Subsec. (d)(1). Pub. L. 109-43, §2(a)(3)(A), inserted after first sentence “For the purposes of this paragraph, the term ‘small business’ means an entity that reported \$30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.”

Subsec. (d)(2)(A). Pub. L. 109-43, §2(a)(3)(B), struck out cl. (i) designation and heading before “For purposes”, substituted “paragraph,” for “subsection,” and “\$100,000,000” for “\$30,000,000”, and struck out heading and text of clause (ii). Text read as follows: “The Secretary may adjust the \$30,000,000 threshold established in clause (i) if the Secretary has evidence from actual experience that this threshold results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 16 percent or more than would occur without small business exemptions and lower fee rates. To adjust this threshold, the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the new threshold.”

Subsec. (d)(2)(C). Pub. L. 109-43, §2(a)(7), substituted “subsection (c)(1)” for “subsection (c)(5)”.

Subsec. (e)(2)(A). Pub. L. 109-43, §2(a)(4), substituted “\$100,000,000” for “\$30,000,000”.

Subsec. (e)(2)(C). Pub. L. 109-43, §2(a)(7), substituted “subsection (c)(1)” for “subsection (c)(5)” in cls. (i) and (ii).

Subsec. (g)(1)(B)(i). Pub. L. 109-43, §2(a)(5)(A)(i), added cl. (i) and struck out former cl. (i) which read as follows: “For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is equal to or greater than the sum of—

“(I) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2003;

“(II) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2004; and

“(III) \$205,720,000 multiplied by the adjustment factor applicable to fiscal year 2005.”

Subsec. (g)(1)(B)(ii). Pub. L. 109-43, §2(a)(5)(A)(ii), added introductory provisions and struck out former introductory provisions which read as follows: “For fiscal year 2005, if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is less than the sum that applies under clause (i) for fiscal year 2005, the following applies:”

Subsec. (g)(1)(C). Pub. L. 109-43, §2(a)(5)(B)(i), substituted “2005 and” for “2003 through” and inserted “more than 1 percent” after “years, is”.

Subsec. (g)(1)(C)(ii). Pub. L. 109-43, §2(a)(5)(B)(ii), substituted “amount that applies” for “sum that applies”.

Subsec. (g)(1)(D)(i). Pub. L. 109-43, §2(a)(5)(C), inserted “more than 1 percent” after “year, is”.

Subsec. (h)(3)(D), (E). Pub. L. 109-43, §2(a)(6), added subpar. (D) and struck out former subpars. (D) and (E) which read as follows:

“(D) \$32,615,000 for fiscal year 2006; and

“(E) \$35,000,000 for fiscal year 2007.”

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.

Subsec. (a). Pub. L. 108-214, §2(d)(2)(A), designated introductory provisions of subsec. (a) as par. (1), inserted heading, substituted “this section.” for “this section as follows:”, and redesignated former par. (1) as (2).

Subsec. (a)(1)(A). Pub. L. 108-214, §2(a)(2)(A)(i), substituted, in introductory provisions, “subsections (d) and (e)” for “subsection (d)”, in cl. (iv), “clause (i)” for “clause (i), subject to any adjustment under subsection

(c)(3) of this section”, and, in cl. (vii), “clause (i), subject to any adjustment under subsection (e)(2)(C)(ii)” for “clause (i), subject to any adjustment under subsection (c)(3) of this section and any adjustment under subsection (e)(2)(C)(ii)”.

Subsec. (a)(1)(D)(i), (ii). Pub. L. 108-214, §2(a)(2)(A)(ii), substituted “application, report,” for “application”.

Subsec. (d)(1). Pub. L. 108-214, §2(d)(2)(B)(i), substituted “subsection (a)(2)(A)” for “subsection (a)(1)(A)” in last sentence.

Subsec. (d)(2)(B). Pub. L. 108-214, §2(a)(2)(B), substituted “firms, which show” for “firms. which show” in second sentence.

Subsec. (e)(1). Pub. L. 108-214, §2(a)(2)(C)(i), (d)(2)(B)(ii), substituted “For fiscal year 2004 and each subsequent fiscal year, where” for “Where” and “subsection (a)(2)(A)(vii)” for “subsection (a)(1)(A)(vii)”.

Subsec. (e)(2)(B). Pub. L. 108-214, §2(a)(2)(C)(ii)(I), substituted “firms, which show” for “firms. which show”.

Subsec. (e)(2)(C). Pub. L. 108-214, §2(a)(2)(C)(ii)(II), (d)(2)(B)(iii), substituted “For fiscal year 2004 and each subsequent fiscal year, where” for “Where” in cl. (i), “subsection (a)(2)(A)(vii)” for “subsection (a)(1)(A)(vii)” in cls. (i) and (ii), and “subsection (a)(2)(A)(i)” for “subsection (a)(1)(A)(i)” in cl. (ii).

Subsec. (f). Pub. L. 108-214, §2(a)(2)(D), struck out “for filing” after “accepted”.

Subsec. (h)(2)(B). Pub. L. 108-214, §2(a)(2)(E), designated existing provisions as cl. (i), inserted heading, redesignated former cls. (i) and (ii) as subcls. (I) and (II), respectively, of cl. (i), redesignated former subcls. (I) and (II) of cl. (i) as items (aa) and (bb), respectively, of cl. (i)(II), and added cl. (ii).

Subsec. (j). Pub. L. 108-214, §2(d)(2)(B)(iv), substituted “subsection (a)(2)(D)” for “subsection (a)(1)(D)”.

EFFECTIVE AND TERMINATION DATES OF 2007 AMENDMENT

Amendment by Pub. L. 110-85 effective Oct. 1, 2007, except for certain premarket fees under this subpart, and ceases to be effective Oct. 1, 2012, see sections 216 and 217 of Pub. L. 110-85, set out as notes under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section effective Oct. 26, 2002, except for certain premarket fees, and ceases to be effective Oct. 1, 2007, see sections 106 and 107 of Pub. L. 107-250, set out as notes under section 379i of this title.

FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS

Pub. L. 107-250, title I, §102(b), Oct. 26, 2002, 116 Stat. 1600, as amended by Pub. L. 108-214, §2(d)(2)(C), (3)(B), Apr. 1, 2004, 118 Stat. 577, provided that: “A person submitting a premarket report to the Secretary of Health and Human Services is exempt from the fee under section 738(a)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j(a)(2)(A)(ii)] (as added by subsection (a) of this section) if—

“(1) the premarket report is the first such report submitted to the Secretary by the person; and

“(2) before October 1, 2002, the person submitted a premarket application to the Secretary for the same device as the device for which the person is submitting the premarket report.”

§ 379j-1. Reauthorization; reporting requirements

(a) Reports

(1) Performance report

For fiscal years 2008 through 2012, 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(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 device premarket applications and reports, supplements, and premarket notifications in the cohort.

(2) Fiscal report

For fiscal years 2008 through 2012, 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.

(3) Public availability

The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

(b) 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 device 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)(1);
- (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 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, §738A, as added Pub. L. 110-85, title II, §213, Sept. 27, 2007, 121 Stat. 850.)

TERMINATION OF SECTION

For termination of section by section 217 of Pub. L. 110-85, see Effective and Termination Dates note below.

REFERENCES IN TEXT

Section 201(c) of the Food and Drug Administration Amendments Act of 2007, referred to in subsec. (a)(1), is section 201(c) of Pub. L. 110-85, which is set out as a note under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section effective Oct. 1, 2007, except for certain premarket fees under this subpart, and ceases to be effective

tive Jan. 31, 2013, see sections 216 and 217 of Pub. L. 110-85, set out as Effective and Termination Dates of 2007 Amendment notes under section 379i of this title.

SUBPART 4—FEES RELATING TO ANIMAL DRUGS

TERMINATION OF SUBPART

For termination of subpart by section 5 of Pub. L. 108-130, see Termination Date note set out under section 379j-11 of this title.

§ 379j-11. Definitions

For purposes of this subpart:

(1) The term “animal drug application” means an application for approval of any new animal drug submitted under section 360b(b)(1) of this title. Such term does not include either a new animal drug application submitted under section 360b(b)(2) of this title or a supplemental animal drug application.

(2) The term “supplemental animal drug application” means—

(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

(B) a request to the Secretary to approve a change to an application approved under section 360b(c)(2) of this title for which data with respect to safety or effectiveness are required.

(3) The term “animal drug product” means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

(4) The term “animal drug establishment” means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

(5) The term “investigational animal drug submission” means—

(A) the filing of a claim for an investigational exemption under section 360b(j) of this title for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

(6) The term “animal drug sponsor” means either an applicant named in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 360 of this title, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

(7) The term “final dosage form” means, with respect to an animal drug product, a fin-

ished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

(8) The term “process for the review of animal drug applications” means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary’s review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not such activities after an animal drug has been approved.

(9) The term “costs of resources allocated for the process for the review of animal drug applications” means the expenses incurred in connection with the process for the review of animal drug applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities,

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

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, mainte-