

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-

nance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

(D) collecting fees under section 379j-12 of this title and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(10) The term “adjustment factor” applicable to a fiscal year refers to the formula set forth in section 379g(8) of this title with the base or comparator year being 2003.

(11) The term “affiliate” refers to the definition set forth in section 379g(11) of this title.

(June 25, 1938, ch. 675, §739, as added Pub. L. 108-130, §3, Nov. 18, 2003, 117 Stat. 1361; amended Pub. L. 110-85, title I, §109, Sept. 27, 2007, 121 Stat. 842.)

#### TERMINATION OF SECTION

*For termination of section by section 5 of Pub. L. 108-130, see Termination Date note below.*

#### AMENDMENTS

2007—Pub. L. 110-85, §109(a), substituted “subpart” for “part” in introductory provisions.

Par. (11). Pub. L. 110-85, §109(b), substituted “379g(11)” for “379g(9)”.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110-85 effective 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.

#### TERMINATION DATE

Pub. L. 108-130, §5, Nov. 18, 2003, 117 Stat. 1371, provided that: “The amendments made by section 3 [enacting this subpart] shall not be in effect after October 1, 2008, and section 4 [enacting provisions set out as a note below] shall not be in effect after 120 days after such date.”

#### FINDINGS

Pub. L. 108-130, §2, Nov. 18, 2003, 117 Stat. 1361, provided that: “Congress finds as follows:

“(1) Prompt approval of safe and effective new animal drugs is critical to the improvement 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 review of new animal drug applications.

“(3) The fees authorized by this Act [enacting this subpart and provisions set out as notes under this section and section 301 of this title] will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 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 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.”

#### ACCOUNTABILITY AND REPORTS

Pub. L. 108-130, §4, Nov. 18, 2003, 117 Stat. 1370, provided that:

“(a) PUBLIC ACCOUNTABILITY.—

“(1) CONSULTATION.—In developing recommendations to Congress for the goals and plans for meeting the goals for the process for the review of animal drug applications for the fiscal years after fiscal year 2008, and for the reauthorization of sections 739 and 740 of the Federal Food, Drug, and Cosmetic Act (as added by section 3) [42 U.S.C. 379j-11, 379j-12], 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, veterinary professionals, representatives of consumer advocacy groups, and the regulated industry.

“(2) RECOMMENDATIONS.—The Secretary shall—

“(A) publish in the Federal Register recommendations under paragraph (1), after negotiations with the regulated industry;

“(B) present the recommendations to the Committees referred to in that paragraph;

“(C) hold a meeting at which the public may comment on the recommendations; and

“(D) provide for a period of 30 days for the public to provide written comments on the recommendations.

“(b) PERFORMANCE REPORTS.—Beginning with fiscal year 2004, not later than 60 days after the end of each fiscal year during which fees are collected under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [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 2(3) of this Act [set out as a note above] toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

“(c) FISCAL REPORT.—Beginning with fiscal year 2004, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (b), 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 during such fiscal year for which the report is made.”

### § 379j-12. Authority to assess and use animal drug fees

#### (a) Types of fees

Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

#### (1) Animal drug application and supplement fee

##### (A) In general

Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

(i) A fee established in subsection (b) of this section for an animal drug application; and