ceived on or after Oct. 1, 2022, see section 2008 of Pub. L. 117–180, set out as a note under section 360d of this title.

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by section 203 of Pub. L. 115–52 effective Oct. 1, 2017, with fees under this subpart to be assessed for all submissions listed in subsec. (a)(2)(A) of this section received on or after Oct. 1, 2017, see section 209 of Pub. L. 115–52, set out as a note under section 379i of this title.

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 submissions listed in subsection (a)(2)(A) of this section received on or after Oct. 1, 2012, see section 206 of Pub. L. 112–144, set out as a note under section 379i of this title.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–85 effective Oct. 1, 2007, except for certain premarket fees under this subpart, see section 216 of Pub. L. 110–85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Oct. 1, 2027, see section 2007(a) of Pub. L. 117–180, set out as a note under section 379i of this title.

Section effective Oct. 26, 2002, except for certain premarket fees, see section 106 of Pub. L. 107–250, set out as a note 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

(A) In general

(i) General requirements

Beginning with fiscal year 2023, for each fiscal year for 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 annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(ii) Additional information

Beginning with fiscal year 2023, the annual report under this subparagraph shall include the progress of the Center for Devices and Radiological Health in achieving the goals, and future plans for meeting the goals, including—

(I) the number of premarket applications filed under section 360e of this title per fiscal year for each review division;

(II) the number of reports submitted under section 360(k) of this title per fiscal year for each review division;

(III) the number of expedited development and priority review designations under section 360e–3[1] of this title per fiscal year;

(IV) the number of investigational device exemption applications submitted under section 360j(g) of this title per fiscal year, including for each review division; and

(V) the number of expedited development and priority review requests and designations under section 360e–3 of this title per fiscal year, including for each review division.

Nothing in this clause shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 331(j) of this title or section 1905 of title 18 or that is subject to withholding under section 552(b)(4) of title 5.

(iii) Real time reporting

(I) In general

Not later than 30 calendar days after the end of the second quarter of fiscal year 2023, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subclause (II) on the internet website of the Food and Drug Administration for such quarter and on a cumulative basis for such fiscal year, and may remove duplicative data from the annual report under this subparagraph.

(II) Data

The Secretary shall post the following data in accordance with subclause (I):

(aa) The number and titles of draft and final guidance on topics related to the process for the review of devices, and whether such guidances were issued as required by statute or pursuant to the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022; and

(bb) The number and titles of public meetings held on topics related to the process for the review of devices, and if such meetings were required by statute or pursuant to a commitment under the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022.

[1] See References in Text note below.

(iv) Rationale for MDUFA program changes

Beginning with fiscal year 2023, the Secretary shall include in the annual report under paragraph (1)—

(I) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 379j of this title, and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(II) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of device applications, including identifying—

(aa) drivers of such changes; and

(bb) changes in the average total cost per full-time equivalent in the medical device review program;

(III) for each of the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required; and

(IV) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of medical device application types.

(v) Analysis

For each fiscal year, the Secretary shall include in the report under clause (i) an analysis of the following:

(I) The difference between the aggregate number of premarket applications filed under section 360e of this title and aggregate reports submitted under section 360(k) of this title and the aggregate number of major deficiency letters, not approvable letters, and denials for such applications issued by the agency, accounting for—

(aa) the number of applications filed and reports submitted during one fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(bb) the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022 for the applicable fiscal year.

(II) Relevant data to determine whether the Center for Devices and Radiological Health has met performance enhancement goals identified by the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022 for the applicable fiscal year.

(III) The most common causes and trends for external or other circumstances affecting the ability of the Center for Devices and Radiological Health, the Office of Regulatory Affairs, or the Food and Drug Administration to meet review time and performance enhancement goals identified by the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022.

(B) Publication

With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022, the Secretary shall make such information publicly available on the Internet Web site of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

(C) Updates

The Secretary shall include in each report under subparagraph (A) 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) Corrective action report

Beginning with fiscal year 2023, for each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate. The report shall include the following information, as applicable:

(A) Goals met

For each fiscal year, if the Secretary determines, based on the analysis under paragraph (1)(A)(iv), that each of the goals identified by the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022 for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the medical device application review process.

(B) Goals missed

For each of the goals identified by the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022 for

the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(i) a justification for such determination;

(ii) a description of the types of circumstances, in the aggregate, under which applications or reports submitted under section 360e of this title or notifications submitted under section 360(k) of this title missed the review goal times but were approved during the first cycle review, as applicable;

(iii) a summary and any trends with regard to the circumstances for which a review goal was missed; and

(iv) the performance enhancement goals that were not achieved during the previous fiscal year and a description of efforts the Food and Drug Administration has put in place for the fiscal year in which the report is submitted to improve the ability of such agency to meet each such goal for the such[2] fiscal year.

(3) Enhanced communication

(A) Communications with Congress

Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of devices shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

(B) Participation in congressional hearing

Each fiscal year, as applicable and requested, representatives from the Food and Drug Administration shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this subpart.

(4) Fiscal report

For fiscal years 2023 through 2027, 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.

(5) 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.

[2] So in original.

(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 2027, 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) Updates to Congress

The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this part to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(5) 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.

(6) Transmittal of recommendations

Not later than January 15, 2027, 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.

(7) Minutes of negotiation meetings

(A) Public availability

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, not later than 30 days after each such negotiation meeting.

(B) Content

The minutes described under subparagraph (A) shall summarize, in sufficient detail, 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; amended Pub. L. 112–144, title II, §204, July 9, 2012, 126 Stat. 1006; Pub. L. 115–52, title II, §204, title IX, §§903(b), 904(b), Aug. 18, 2017, 131 Stat. 1016, 1078, 1083; Pub. L. 117–180, div. F, title II, §2004, Sept. 30, 2022, 136 Stat. 2153; Pub. L. 117–328, div. FF, title III, §3626(b), Dec. 29, 2022, 136 Stat. 5884.)

TERMINATION OF SECTION

For termination of section by section 2007(b) of Pub. L. 117–180, see Effective and Termination Dates note below.

Editorial Notes

REFERENCES IN TEXT

Section 201(b) of the Medical Device User Fee Amendments of 2022, referred to in subsec. (a)(1)(A), (B), (2), probably should be a reference to section 2001(b) of the Medical Device User Fee Amendments of 2022, title II of div. F of Pub. L. 117–180, which is set out as a note under section 379i of this title. The Medical Device User Fee Amendments of 2022 does not contain a section 201(b).

Section 360e–3 of this title, referred to in subsec. (a)(1)(A)(ii)(III), was in the original a reference to section 515C of act June 25, 1938, which was renumbered section 515B by Pub. L. 115–52, title IX, §901(f)(2), Aug. 18, 2017, 131 Stat. 1077.

Section 2001(b) of the Medical Device User Fee Amendments of 2022, referred to in subsec. (a)(1)(A)(iv)(I), is section 2001(b) of title II of div. F of Pub. L. 117–180, which is set out as a note under section 379i of this title.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–180, §2004(a)(1), (2), substituted ''fiscal year 2023'' for ''fiscal year 2018'' and ''Medical Device User Fee Amendments of 2022'' for ''Medical Device User Fee Amendments of 2017'' wherever appearing.

Subsec. (a)(1)(A)(ii). Pub. L. 117–328, §3626(b)(1)(A)(iii), inserted concluding provisions.

Subsec. (a)(1)(A)(ii)(IV), (V). Pub. L. 117–328, §3626(b)(1)(A), added subcls. (IV) and (V).

Subsec. (a)(1)(A)(iv). Pub. L. 117–180, §2004(a)(3)(B), substituted ''fiscal year 2023'' for ''fiscal year 2020'' in introductory provisions of cl. (iv) relating to rationale for MDUFA program changes.

Subsec. (a)(1)(A)(iv)(I). Pub. L. 117–328, §3626(b)(1)(B)(i), amended subcl. (I) generally. Prior to amendment, subcl. (I) read as follows: ''data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022 and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;''.

Subsec. (a)(1)(A)(iv)(II). Pub. L. 117–328, §3626(b)(1)(B)(ii), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: ''data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of devices, including identifying drivers of such changes; and''.

Subsec. (a)(1)(A)(iv)(IV). Pub. L. 117–328, §3626(b)(1)(B)(iii), (iv), added subcl. (IV).

Subsec. (a)(1)(A)(v). Pub. L. 117–180, §2004(a)(3)(A), redesignated cl. (iv) relating to analysis to be included in report as (v).

Subsec. (a)(4). Pub. L. 117–180, §2004(a)(4), substituted ''2023 through 2027'' for ''2018 through 2022''.

Subsec. (b)(1). Pub. L. 117–180, §2004(b)(1), substituted ''2027'' for ''2022'' in introductory provisions.

Subsec. (b)(4). Pub. L. 117–328, §3626(b)(2)(B), added par. (4). Former par. (4) redesignated (5).

Subsec. (b)(5). Pub. L. 117–328, §3626(b)(2)(A), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Pub. L. 117–180, §2004(b)(2), substituted ''2027'' for ''2022''.

Subsec. (b)(6), (7). Pub. L. 117–328, §3626(b)(2)(A), redesignated pars. (5) and (6) as (6) and (7), respectively.

Subsec. (b)(7)(A). Pub. L. 117–328, §3626(b)(2)(C)(i), substituted ''The'' for ''Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the'' and inserted '', not later than 30 days after each such negotiation meeting'' before period at end.

Subsec. (b)(7)(B). Pub. L. 117–328, §3626(b)(2)(C)(ii), inserted '', in sufficient detail,'' after ''shall summarize''.

2017—Subsec. (a)(1)(A). Pub. L. 115–52, §903(b), designated existing provisions as cl. (i), inserted heading, and added cls. (ii), (iii), and (iv) related to rationale for MDUFA program changes.

Subsec. (a)(1)(A)(i). Pub. L. 115–52, §204(a)(1)(A), substituted ''2018'' for ''2013'' and ''the Medical Device User Fee Amendments of 2017'' for ''the Medical Device User Fee Amendments of 2012''.

Subsec. (a)(1)(A)(iv). Pub. L. 115–52, §904(b)(1), added cl. (iv) relating to analysis to be included in report.

Subsec. (a)(1)(B). Pub. L. 115–52, §204(a)(1)(B), substituted ''the Medical Device User Fee Amendments of 2017'' for ''the Medical Device User Fee Amendments Act of 2012''.

Subsec. (a)(2), (3). Pub. L. 115–52, §904(b)(2)(B), added pars. (2) and (3). Former pars. (2) and (3) redesignated (4) and (5), respectively.

Subsec. (a)(4). Pub. L. 115–52, §904(b)(2)(A), redesignated par. (2) as (4).

Pub. L. 115–52, §204(a)(2), which directed amendment of par. (2), effective Oct. 1, 2017, by substituting ''2018 through 2022'' for ''2013 through 2017'', was executed by making the substitution in par. (4) to reflect the probable intent of Congress and the redesignation of par. (2) as (4), effective Aug. 18, 2017, by Pub. L. 115–52, §904(b)(2)(A). See Amendment note above.

Subsec. (a)(5). Pub. L. 115–52, §904(b)(2)(A), redesignated par. (3) as (5).

Subsec. (b)(1). Pub. L. 115–52, § 204(b)(1), substituted ''2022'' for ''2017'' in introductory provisions.

Subsec. (b)(5). Pub. L. 115–52, § 204(b)(2), substituted ''2022'' for ''2017''.

2012—Subsec. (a)(1). Pub. L. 112–144, § 204(b)(1), added par. (1) and struck out former par. (1). Prior to amendment, text read as follows: ''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.''

Subsec. (a)(2). Pub. L. 112–144, § 204(b)(2), substituted ''2013 through 2017'' for ''2008 through 2012''.

Subsec. (b)(1). Pub. L. 112–144, § 204(a)(1), substituted ''2017'' for ''2012''.

Subsec. (b)(5). Pub. L. 112–144, § 204(a)(2), substituted ''2017'' for ''2012''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117–180 effective Oct. 1, 2022, with fees under this subpart to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2022, see section 2008 of Pub. L. 117–180, set out as a note under section 360d of this title.

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by section 204 of Pub. L. 115–52 effective Oct. 1, 2017, with fees under this subpart to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2017, see section 209 of Pub. L. 115–52, set out as a note under section 379i of this title.

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 submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2012, see section 206 of Pub. L. 112–144, set out as a note under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Pub. L. 117–180, div. F, title II, § 2007(b), Sept. 30, 2022, 136 Stat. 2154, provided that: ''Section 738A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1) shall cease to be effective January 31, 2028.''

Pub. L. 115–52, title II, § 210(b), Aug. 18, 2017, 131 Stat. 1020, which provided that this section would cease to be effective Jan. 31, 2023, was repealed by Pub. L. 117–180, div. F, title II, § 2007(c), Sept. 30, 2022, 136 Stat. 2154.

[Pub. L. 117–180, div. F, title II, § 2007(c), Sept. 30, 2022, 136 Stat. 2154, provided that the repeal of section 210(b) of Pub. L. 115–52, formerly set out above, is effective Oct. 1, 2022.]

Section effective Oct. 1, 2007, except for certain premarket fees under this subpart, see section 216 of Pub. L. 110–85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379i of this title.

SUBPART 4—FEES RELATING TO ANIMAL DRUGS

TERMINATION OF SUBPART

For termination of subpart by section 2307(a), (b) of Pub. L. 118–15, see Termination Date note set out under section 379j–11 of this title and Effective and Termination Dates note set out under section 379j–13 of this title.

§ 379j–11. Definitions

For purposes of this subpart:

(1)(A) The term ''animal drug application'' means—

(i) an application for approval of any new animal drug submitted under section 360b(b)(1) of this title; or

(ii) an application for conditional approval of a new animal drug submitted under section 360ccc of this title.

(B) 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 that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, 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-