

One Hundred Tenth Congress
of the
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Thursday,
the third day of January, two thousand and eight*

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, to establish a program of fees relating to generic new animal drugs, to make certain technical corrections to the Food and Drug Administration Amendments Act of 2007, and for other purposes.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

- Sec. 1. Table of contents.
- Sec. 2. References in Act.

TITLE I—ANIMAL DRUG USER FEE AMENDMENTS

- Sec. 101. Short title; finding.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use animal drug fees.
- Sec. 104. Reauthorization; reporting requirements.
- Sec. 105. Antimicrobial animal drug distribution reports.
- Sec. 106. Savings clause.
- Sec. 107. Effective date.
- Sec. 108. Sunset dates.

TITLE II—ANIMAL GENERIC DRUG USER FEE

- Sec. 201. Short title; findings.
- Sec. 202. Fees relating to abbreviated applications for generic new animal drugs.
- Sec. 203. Accountability and reports.
- Sec. 204. Sunset dates.

TITLE III—TECHNICAL CORRECTIONS TO FDAAA

- Sec. 301. Consideration of certain petitions.
- Sec. 302. Registry and results data bank.

SEC. 2. REFERENCES IN ACT.

Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

**TITLE I—ANIMAL DRUG USER FEE
AMENDMENTS**

SEC. 101. SHORT TITLE; FINDING.

(a) **SHORT TITLE.**—This title may be cited as the “Animal Drug User Fee Amendments of 2008”.

(b) **FINDING.**—Congress finds that the fees authorized by the amendments made in 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, 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.

SEC. 102. DEFINITIONS.

Section 739 (21 U.S.C. 379j–11) is amended—

(1) in paragraph (6), by striking “, except for an approved application for which all subject products have been removed from listing under section 510” and inserting “that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary”;

(2) in paragraph (8)(H), by striking “but not such activities after an animal drug has been approved” and inserting “but not after such application has been approved”;

(3) in paragraph (10), by striking “year being 2003” and inserting “month being October 2002”;

(4) by redesignating paragraph (11) as paragraph (12); and

(5) by inserting after paragraph (10) the following:

“(11) The term ‘person’ includes an affiliate thereof.”.

SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

(a) TYPES OF FEES.—Section 740(a) (21 U.S.C. 379j–12(a)) is amended—

(1) in paragraph (1)(A)(i), by inserting after “for an animal drug application” the following: “, except an animal drug application subject to the criteria set forth in section 512(d)(4)”;

and

(2) by amending paragraph (1)(A)(ii) to read as follows:

“(ii) A fee established in subsection (b), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

“(I) a supplemental animal drug application for which safety or effectiveness data are required; and

“(II) an animal drug application subject to the criteria set forth in section 512(d)(4).”.

(b) FEE AMOUNTS.—

(1) TOTAL FEE REVENUES FOR APPLICATION AND SUPPLEMENT FEES.—Section 740(b)(1) (21 U.S.C. 379j–12(b)(1)) is amended—

(A) by striking “and supplemental animal drug application fees” and inserting “and supplemental and other animal drug application fees”; and

(B) by striking “\$1,250,000” and all that follows through the period at the end and inserting “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.”.

(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—Section 740(b)(2) (21 U.S.C. 379j–12(b)(2)) is amended by striking “\$1,250,000” and all that follows through the period at the end and inserting “\$3,815,000 for fiscal year 2009, \$4,320,000

for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.”.

(3) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—Section 740(b)(3) (21 U.S.C. 379j–12(b)(3)) is amended by striking “\$1,250,000” and all that follows through the period at the end and inserting “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.”.

(4) TOTAL FEE REVENUES FOR SPONSOR FEES.—Section 740(b)(4) (21 U.S.C. 379j–12(b)(4)) is amended by striking “\$1,250,000” and all that follows through the period at the end and inserting “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.”.

(c) ADJUSTMENTS TO FEES.—Section 740(c) (21 U.S.C. 379j–12(c)) is amended—

(1) by striking paragraph (1);

(2) by redesignating paragraphs (2) through (5) as paragraphs (1) through (4), respectively;

(3) in paragraph (1), as so redesignated—

(A) in the matter preceding subparagraph (A), by striking “After the fee revenues are adjusted for inflation in accordance with paragraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004” and inserting “The fee revenues shall be adjusted each fiscal year after fiscal year 2009”; and

(B) in subparagraph (B), by striking “, as adjusted for inflation under paragraph (1)”;

(4) in paragraph (2), as so redesignated—

(A) by striking “2008” each place it appears and inserting “2013”; and

(B) by striking “2009” and inserting “2014”.

(d) AUTHORIZATION OF APPROPRIATIONS.—Subparagraphs (A) through (E) of section 740(g)(3) (21 U.S.C. 379j–12(g)(3)) are amended to read as follows:

“(A) \$15,260,000 for fiscal year 2009;

“(B) \$17,280,000 for fiscal year 2010;

“(C) \$19,448,000 for fiscal year 2011;

“(D) \$21,768,000 for fiscal year 2012; and

“(E) \$24,244,000 for fiscal year 2013;”.

(e) OFFSET.—Section 740(g)(4) (21 U.S.C. 379j–12(g)(4)) is amended to read as follows:

“(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for fiscal years 2009 through 2011 and the amount of fees estimated to be collected under this section for fiscal year 2012 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2009 through 2012, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2013.”.

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 4 of subchapter C of chapter VII (21 U.S.C. 379j–11 et seq.) is amended by inserting after section 740 the following:

“SEC. 740A. REAUTHORIZATION; REPORTING REQUIREMENTS.

“(a) **PERFORMANCE REPORT.**—Beginning with fiscal year 2009, not later than 60 days after the end of each fiscal year during which fees are collected under this part, 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(b) of the Animal Drug User Fee Amendments of 2008 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.

“(b) **FISCAL REPORT.**—Beginning with fiscal year 2009, not later than 120 days after the end of each fiscal year during which fees are collected under this part, 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.

“(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 animal drug applications for the first 5 fiscal years after fiscal year 2013, and for the reauthorization of this part 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) veterinary 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 part, 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 part; and

“(D) publish the comments on the Food and Drug Administration’s Internet Web site.

“(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part 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, 2013, 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 Internet 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.”.

SEC. 105. ANTIMICROBIAL ANIMAL DRUG DISTRIBUTION REPORTS.

(a) REPORTS.—Section 512(l) (21 U.S.C. 360b(l)) is amended by adding at the end the following:

“(3)(A) In the case of each new animal drug described in paragraph (1) that contains an antimicrobial active ingredient, the sponsor of the drug shall submit an annual report to the Secretary on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product.

“(B) Each report under this paragraph shall specify the amount of each antimicrobial active ingredient—

“(i) by container size, strength, and dosage form;

“(ii) by quantities distributed domestically and quantities exported; and

“(iii) by dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.

“(C) Each report under this paragraph shall—

“(i) be submitted not later than March 31 each year;

“(ii) cover the period of the preceding calendar year; and

“(iii) include separate information for each month of such calendar year.

“(D) The Secretary may share information reported under this paragraph with the Antimicrobial Resistance Task Force established under section 319E of the Public Health Service Act.

“(E) The Secretary shall make summaries of the information reported under this paragraph publicly available, except that—

“(i) the summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; and

“(ii) the data shall be reported in a manner consistent with protecting both national security and confidential business information.”

(b) **FIRST REPORT.**—For each new animal drug that is subject to the reporting requirement under section 512(l)(3) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and for which an approval of an application filed pursuant to section 512(b) or 571 of such Act is in effect on the date of the enactment of this title, the Secretary of Health and Human Services shall require the sponsor of the drug to submit the first report under such section 512(l)(3) for the drug not later than March 31, 2010.

(c) **SEPARATE REPORT.**—The reports required under section 512(l)(3) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be separate from periodic drug experience reports that are required under section 514.80(b)(4) of title 21, Code of Federal Regulations (as in effect on the date of the enactment of this title).

SEC. 106. SAVINGS CLAUSE.

Notwithstanding section 5 of the Animal Drug User Fee Act of 2003 (21 U.S.C. 379j–11 note), and notwithstanding the amendments made by this title, part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such day) that on or after September 1, 2003, but before October 1, 2008, 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 2009.

SEC. 107. EFFECTIVE DATE.

The amendments made by sections 102, 103, and 104 shall take effect on October 1, 2008, and fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this title, shall be assessed for all animal drug applications and supplemental animal drug applications received on or after such date, regardless of the date of the enactment of this title.

SEC. 108. SUNSET DATES.

(a) **AUTHORIZATION.**—The amendments made by sections 102 and 103 cease to be effective October 1, 2013.

(b) **REPORTING REQUIREMENTS.**—The amendment made by section 104 ceases to be effective January 31, 2014.

TITLE II—ANIMAL GENERIC DRUG USER FEE

SEC. 201. SHORT TITLE; FINDINGS.

(a) **SHORT TITLE.**—This title may be cited as the “Animal Generic Drug User Fee Act of 2008”.

(b) **FINDINGS.**—Congress finds as follows:

(1) Prompt approval of abbreviated applications for safe and effective generic new animal drugs will reduce animal healthcare costs and promote the well-being 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 the review of abbreviated applications for the approval of generic new animal drugs.

(3) The fees authorized by this title will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified 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.

SEC. 202. FEES RELATING TO ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.

(a) **REDESIGNATION.**—Chapter VII (21 U.S.C. 371 et seq.) is amended by redesignating sections 741, 742, and 746 as sections 745, 746, and 749, respectively.

(b) **AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.**—Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

“PART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS

“SEC. 741. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

“(a) **TYPES OF FEES.**—Beginning with respect to fiscal year 2009, the Secretary shall assess and collect fees in accordance with this section as follows:

“(1) **ABBREVIATED APPLICATION FEE.**—

“(A) **IN GENERAL.**—Each person that submits, on or after July 1, 2008, an abbreviated application for a generic