

110TH CONGRESS
2^D SESSION

H. R. 6432

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.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. TABLE OF CONTENTS.**

4 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.

5 **SEC. 2. REFERENCES IN ACT.**

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

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

12 **SEC. 101. SHORT TITLE; FINDING.**

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

1 (b) FINDING.—Congress finds that the fees author-
2 ized by the amendments made in this title will be dedi-
3 cated toward expediting the animal drug development
4 process and the review of new and supplemental animal
5 drug applications and investigational animal drug submis-
6 sions as set forth in the goals identified, for purposes of
7 part 4 of subchapter C of chapter VII of the Federal Food,
8 Drug, and Cosmetic Act, in the letters from the Secretary
9 of Health and Human Services to the Chairman of the
10 Committee on Energy and Commerce of the House of
11 Representatives and the Chairman of the Committee on
12 Health, Education, Labor, and Pensions of the Senate as
13 set forth in the Congressional Record.

14 **SEC. 102. DEFINITIONS.**

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

16 (1) in paragraph (6), by striking “, except for
17 an approved application for which all subject prod-
18 ucts have been removed from listing under section
19 510” and inserting “that has not been withdrawn by
20 the applicant and for which approval has not been
21 withdrawn by the Secretary”;

22 (2) in paragraph (8)(H), by striking “but not
23 such activities after an animal drug has been ap-
24 proved” and inserting “but not after such applica-
25 tion has been approved”;

1 (3) in paragraph (10), by striking “year being
2 2003” and inserting “month being October 2002”;

3 (4) by redesignating paragraph (11) as para-
4 graph (12); and

5 (5) by inserting after paragraph (10) the fol-
6 lowing:

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

9 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
10 **FEES.**

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

13 (1) in paragraph (1)(A)(i), by inserting after
14 “for an animal drug application” the following: “,
15 except an animal drug application subject to the cri-
16 teria set forth in section 512(d)(4)”;

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

19 “(ii) A fee established in subsection
20 (b), in an amount that is equal to 50 per-
21 cent of the amount of the fee under clause
22 (i), for—

23 “(I) a supplemental animal drug
24 application for which safety or effec-
25 tiveness data are required; and

1 “(II) an animal drug application
2 subject to the criteria set forth in sec-
3 tion 512(d)(4).”.

4 (b) FEE AMOUNTS.—

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

8 (A) by striking “and supplemental animal
9 drug application fees” and inserting “and sup-
10 plemental and other animal drug application
11 fees”; and

12 (B) by striking “\$1,250,000” and all that
13 follows through the period at the end and in-
14 serting “\$3,815,000 for fiscal year 2009,
15 \$4,320,000 for fiscal year 2010, \$4,862,000 for
16 fiscal year 2011, \$5,442,000 for fiscal year
17 2012, and \$6,061,000 for fiscal year 2013.”.

18 (2) TOTAL FEE REVENUES FOR PRODUCT
19 FEES.—Section 740(b)(2) (21 U.S.C. 379j–
20 12(b)(2)) is amended by striking “\$1,250,000” and
21 all that follows through the period at the end and
22 inserting “\$3,815,000 for fiscal year 2009,
23 \$4,320,000 for fiscal year 2010, \$4,862,000 for fis-
24 cal year 2011, \$5,442,000 for fiscal year 2012, and
25 \$6,061,000 for fiscal year 2013.”.

1 (3) TOTAL FEE REVENUES FOR ESTABLISH-
2 MENT FEES.—Section 740(b)(3) (21 U.S.C. 379j–
3 12(b)(3)) is amended by striking “\$1,250,000” and
4 all that follows through the period at the end and
5 inserting “\$3,815,000 for fiscal year 2009,
6 \$4,320,000 for fiscal year 2010, \$4,862,000 for fis-
7 cal year 2011, \$5,442,000 for fiscal year 2012, and
8 \$6,061,000 for fiscal year 2013.”.

9 (4) TOTAL FEE REVENUES FOR SPONSOR
10 FEES.—Section 740(b)(4) (21 U.S.C. 379j–
11 12(b)(4)) is amended by striking “\$1,250,000” and
12 all that follows through the period at the end and
13 inserting “\$3,815,000 for fiscal year 2009,
14 \$4,320,000 for fiscal year 2010, \$4,862,000 for fis-
15 cal year 2011, \$5,442,000 for fiscal year 2012, and
16 \$6,061,000 for fiscal year 2013.”.

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

19 (1) by striking paragraph (1);

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

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

23 (A) in the matter preceding subparagraph

24 (A), by striking “After the fee revenues are ad-

25 justed for inflation in accordance with para-

1 graph (1), the fee revenues shall be further ad-
2 justed each fiscal year after fiscal year 2004”
3 and inserting “The fee revenues shall be ad-
4 justed each fiscal year after fiscal year 2009”;
5 and

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

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

10 (A) by striking “2008” each place it ap-
11 pears and inserting “2013”; and

12 (B) by striking “2009” and inserting
13 “2014”.

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

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

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

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

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

21 and

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

23 (e) OFFSET.—Section 740(g)(4) (21 U.S.C. 379j–
24 12(g)(4)) is amended to read as follows:

1 “(4) OFFSET.—If the sum of the cumulative
2 amount of fees collected under this section for fiscal
3 years 2009 through 2011 and the amount of fees es-
4 timated to be collected under this section for fiscal
5 year 2012 exceeds the cumulative amount appro-
6 priated under paragraph (3) for the fiscal years
7 2009 through 2012, the excess amount shall be
8 credited to the appropriation account of the Food
9 and Drug Administration as provided in paragraph
10 (1), and shall be subtracted from the amount of fees
11 that would otherwise be authorized to be collected
12 under this section pursuant to appropriation Acts
13 for fiscal year 2013.”.

14 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.**

15 Part 4 of subchapter C of chapter VII (21 U.S.C.
16 379j–11 et seq.) is amended by inserting after section 740
17 the following:

18 **“SEC. 740A. REAUTHORIZATION; REPORTING REQUIRE-**
19 **MENTS.**

20 “(a) PERFORMANCE REPORT.—Beginning with fiscal
21 year 2009, not later than 60 days after the end of each
22 fiscal year during which fees are collected under this part,
23 the Secretary shall prepare and submit to the Committee
24 on Energy and Commerce of the House of Representatives
25 and the Committee on Health, Education, Labor, and

1 Pensions of the Senate a report concerning the progress
2 of the Food and Drug Administration in achieving the
3 goals identified in the letters described in section 101(b)
4 of the Animal Drug User Fee Amendments of 2008 to-
5 ward expediting the animal drug development process and
6 the review of the new and supplemental animal drug appli-
7 cations and investigational animal drug submissions dur-
8 ing such fiscal year, the future plans of the Food and
9 Drug Administration for meeting the goals, the review
10 times for abbreviated new animal drug applications, and
11 the administrative procedures adopted by the Food and
12 Drug Administration to ensure that review times for ab-
13 breviated new animal drug applications are not increased
14 from their current level due to activities under the user
15 fee program.

16 “(b) FISCAL REPORT.—Beginning with fiscal year
17 2009, not later than 120 days after the end of each fiscal
18 year during which fees are collected under this part, the
19 Secretary shall prepare and submit to the Committee on
20 Energy and Commerce of the House of Representatives
21 and the Committee on Health, Education, Labor, and
22 Pensions of the Senate a report on the implementation
23 of the authority for such fees during such fiscal year and
24 the use, by the Food and Drug Administration, of the fees

1 collected during such fiscal year for which the report is
2 made.

3 “(c) PUBLIC AVAILABILITY.—The Secretary shall
4 make the reports required under subsections (a) and (b)
5 available to the public on the Internet Web site of the
6 Food and Drug Administration.

7 “(d) REAUTHORIZATION.—

8 “(1) CONSULTATION.—In developing rec-
9 ommendations to present to the Congress with re-
10 spect to the goals, and plans for meeting the goals,
11 for the process for the review of animal drug appli-
12 cations for the first 5 fiscal years after fiscal year
13 2013, and for the reauthorization of this part for
14 such fiscal years, the Secretary shall consult with—

15 “(A) the Committee on Energy and Com-
16 merce of the House of Representatives;

17 “(B) the Committee on Health, Education,
18 Labor, and Pensions of the Senate;

19 “(C) scientific and academic experts;

20 “(D) veterinary professionals;

21 “(E) representatives of patient and con-
22 sumer advocacy groups; and

23 “(F) the regulated industry.

1 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
2 negotiations with the regulated industry on the reau-
3 thorization of this part, the Secretary shall—

4 “(A) publish a notice in the Federal Reg-
5 ister requesting public input on the reauthoriza-
6 tion;

7 “(B) hold a public meeting at which the
8 public may present its views on the reauthoriza-
9 tion, including specific suggestions for changes
10 to the goals referred to in subsection (a);

11 “(C) provide a period of 30 days after the
12 public meeting to obtain written comments from
13 the public suggesting changes to this part; and

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

16 “(3) PERIODIC CONSULTATION.—Not less fre-
17 quently than once every 4 months during negotia-
18 tions with the regulated industry, the Secretary shall
19 hold discussions with representatives of veterinary,
20 patient, and consumer advocacy groups to continue
21 discussions of their views on the reauthorization and
22 their suggestions for changes to this part as ex-
23 pressed under paragraph (2).

1 “(4) PUBLIC REVIEW OF RECOMMENDA-
2 TIONS.—After negotiations with the regulated indus-
3 try, the Secretary shall—

4 “(A) present the recommendations devel-
5 oped under paragraph (1) to the Congressional
6 committees specified in such paragraph;

7 “(B) publish such recommendations in the
8 Federal Register;

9 “(C) provide for a period of 30 days for
10 the public to provide written comments on such
11 recommendations;

12 “(D) hold a meeting at which the public
13 may present its views on such recommenda-
14 tions; and

15 “(E) after consideration of such public
16 views and comments, revise such recommenda-
17 tions as necessary.

18 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
19 Not later than January 15, 2013, the Secretary
20 shall transmit to the Congress the revised rec-
21 ommendations under paragraph (4), a summary of
22 the views and comments received under such para-
23 graph, and any changes made to the recommenda-
24 tions in response to such views and comments.

25 “(6) MINUTES OF NEGOTIATION MEETINGS.—

1 “(A) PUBLIC AVAILABILITY.—Before pre-
2 senting the recommendations developed under
3 paragraphs (1) through (5) to the Congress, the
4 Secretary shall make publicly available, on the
5 Internet Web site of the Food and Drug Ad-
6 ministration, minutes of all negotiation meet-
7 ings conducted under this subsection between
8 the Food and Drug Administration and the reg-
9 ulated industry.

10 “(B) CONTENT.—The minutes described
11 under subparagraph (A) shall summarize any
12 substantive proposal made by any party to the
13 negotiations as well as significant controversies
14 or differences of opinion during the negotiations
15 and their resolution.”.

16 **SEC. 105. ANTIMICROBIAL ANIMAL DRUG DISTRIBUTION**
17 **REPORTS.**

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

20 “(3)(A) In the case of each new animal drug de-
21 scribed in paragraph (1) that contains an antimicrobial
22 active ingredient, the sponsor of the drug shall submit an
23 annual report to the Secretary on the amount of each anti-
24 microbial active ingredient in the drug that is sold or dis-

1 tributed for use in food-producing animals, including in-
2 formation on any distributor-labeled product.

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

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

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

9 “(iii) by dosage form, including, for each such
10 dosage form, a listing of the target animals, indica-
11 tions, and production classes that are specified on
12 the approved label of the product.

13 “(C) Each report under this paragraph shall—

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

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

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

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

1 “(E) The Secretary shall make summaries of the in-
2 formation reported under this paragraph publicly avail-
3 able, except that—

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

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

11 (b) FIRST REPORT.—For each new animal drug that
12 is subject to the reporting requirement under section
13 512(l)(3) of the Federal Food, Drug, and Cosmetic Act,
14 as added by subsection (a), and for which an approval of
15 an application filed pursuant to section 512(b) or 571 of
16 such Act is in effect on the date of the enactment of this
17 title, the Secretary of Health and Human Services shall
18 require the sponsor of the drug to submit the first report
19 under such section 512(l)(3) for the drug not later than
20 March 31, 2010.

21 (c) SEPARATE REPORT.—The reports required under
22 section 512(l)(3) of the Federal Food, Drug, and Cosmetic
23 Act, as added by subsection (a), shall be separate from
24 periodic drug experience reports that are required under
25 section 514.80(b)(4) of title 21, Code of Federal Regula-

1 tions (as in effect on the date of the enactment of this
2 title).

3 **SEC. 106. SAVINGS CLAUSE.**

4 Notwithstanding section 5 of the Animal Drug User
5 Fee Act of 2003 (21 U.S.C. 379j–11 note), and notwith-
6 standing the amendments made by this title, part 4 of sub-
7 chapter C of chapter VII of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in effect on
9 the day before the date of the enactment of this title, shall
10 continue to be in effect with respect to animal drug appli-
11 cations and supplemental animal drug applications (as de-
12 fined in such part as of such day) that on or after Sep-
13 tember 1, 2003, but before October 1, 2008, were accepted
14 by the Food and Drug Administration for filing with re-
15 spect to assessing and collecting any fee required by such
16 part for a fiscal year prior to fiscal year 2009.

17 **SEC. 107. EFFECTIVE DATE.**

18 The amendments made by sections 102, 103, and 104
19 shall take effect on October 1, 2008, and fees under part
20 4 of subchapter C of chapter VII of the Federal Food,
21 Drug, and Cosmetic Act, as amended by this title, shall
22 be assessed for all animal drug applications and supple-
23 mental animal drug applications received on or after such
24 date, regardless of the date of the enactment of this title.

1 **SEC. 108. SUNSET DATES.**

2 (a) AUTHORIZATION.—The amendments made by
3 sections 102 and 103 cease to be effective October 1,
4 2013.

5 (b) REPORTING REQUIREMENTS.—The amendment
6 made by section 104 ceases to be effective January 31,
7 2014.

8 **TITLE II—ANIMAL GENERIC**
9 **DRUG USER FEE**

10 **SEC. 201. SHORT TITLE; FINDINGS.**

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

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

14 (1) Prompt approval of abbreviated applications
15 for safe and effective generic new animal drugs will
16 reduce animal healthcare costs and promote the well-
17 being of animal health and the public health.

18 (2) Animal health and the public health will be
19 served by making additional funds available for the
20 purpose of augmenting the resources of the Food
21 and Drug Administration that are devoted to the
22 process for the review of abbreviated applications for
23 the approval of generic new animal drugs.

24 (3) The fees authorized by this title will be
25 dedicated toward expediting the generic new animal
26 drug development process and the review of abbre-

1 viated applications for generic new animal drugs,
2 supplemental abbreviated applications for generic
3 new animal drugs, and investigational submissions
4 for generic new animal drugs as set forth in the
5 goals identified in the letters from the Secretary of
6 Health and Human Services to the Chairman of the
7 Committee on Energy and Commerce of the House
8 of Representatives and the Chairman of the Com-
9 mittee on Health, Education, Labor, and Pensions
10 of the Senate as set forth in the Congressional
11 Record.

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

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

17 (b) AUTHORITY TO ASSESS AND USE GENERIC NEW
18 ANIMAL DRUG FEES.—Subchapter C of chapter VII of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379f et seq.) is amended by adding at the end the fol-
21 lowing:

1 “(D) REFUND OF FEE IF APPLICATION RE-
2 FUSED FOR FILING.—The Secretary shall re-
3 fund 75 percent of the fee paid under subpara-
4 graph (B) for any abbreviated application which
5 is refused for filing.

6 “(E) REFUND OF FEE IF APPLICATION
7 WITHDRAWN.—If an abbreviated application is
8 withdrawn after the application was filed, the
9 Secretary may refund the fee or portion of the
10 fee paid under subparagraph (B) if no substan-
11 tial work was performed on the application
12 after the application was filed. The Secretary
13 shall have the sole discretion to refund the fee
14 under this subparagraph. A determination by
15 the Secretary concerning a refund under this
16 subparagraph shall not be reviewable.

17 “(2) GENERIC NEW ANIMAL DRUG PRODUCT
18 FEE.—Each person—

19 “(A) who is named as the applicant in an
20 abbreviated application or supplemental abbrevi-
21 ated application for a generic new animal
22 drug product which has been submitted for list-
23 ing under section 510, and

24 “(B) who, after September 1, 2008, had
25 pending before the Secretary an abbreviated ap-

1 plication or supplemental abbreviated applica-
2 tion,
3 shall pay for each such generic new animal drug
4 product the annual fee established in subsection (b).
5 Such fee shall be payable for the fiscal year in which
6 the generic new animal drug product is first sub-
7 mitted for listing under section 510, or is submitted
8 for relisting under section 510 if the generic new
9 animal drug product has been withdrawn from list-
10 ing and relisted. After such fee is paid for that fiscal
11 year, such fee shall be payable on or before January
12 31 of each year. Such fee shall be paid only once for
13 each generic new animal drug product for a fiscal
14 year in which the fee is payable.

15 “(3) GENERIC NEW ANIMAL DRUG SPONSOR
16 FEE.—

17 “(A) IN GENERAL.—Each person—

18 “(i) who meets the definition of a ge-
19 neric new animal drug sponsor within a
20 fiscal year, and

21 “(ii) who, after September 1, 2008,
22 had pending before the Secretary an abbrevi-
23 ated application, a supplemental abbrevi-
24 ated application, or an investigational
25 submission,

1 shall be assessed an annual fee established
2 under subsection (b). The fee shall be paid on
3 or before January 31 of each year.

4 “(B) AMOUNT OF FEE.—Each generic new
5 animal drug sponsor shall pay only 1 such fee
6 each fiscal year, as follows:

7 “(i) 100 percent of the amount of the
8 generic new animal drug sponsor fee pub-
9 lished for that fiscal year under subsection
10 (c)(3) for an applicant with more than 6
11 approved abbreviated applications.

12 “(ii) 75 percent of the amount of the
13 generic new animal drug sponsor fee pub-
14 lished for that fiscal year under subsection
15 (c)(3) for an applicant with more than 1
16 and fewer than 7 approved abbreviated ap-
17 plications.

18 “(iii) 50 percent of the amount of the
19 generic new animal drug sponsor fee pub-
20 lished for that fiscal year under subsection
21 (c)(3) for an applicant with 1 or fewer ap-
22 proved abbreviated applications.

23 “(b) FEE AMOUNTS.—Except as provided in sub-
24 section (a)(1) and subsections (c), (d), (f), and (g), the

1 fees required under subsection (a) shall be established to
2 generate fee revenue amounts as follows:

3 “(1) TOTAL FEE REVENUES FOR APPLICATION
4 FEES.—The total fee revenues to be collected in ab-
5 breviated application fees under subsection (a)(1)
6 shall be \$1,449,000 for fiscal year 2009, \$1,532,000
7 for fiscal year 2010, \$1,619,000 for fiscal year
8 2011, \$1,712,000 for fiscal year 2012, and
9 \$1,809,000 for fiscal year 2013.

10 “(2) TOTAL FEE REVENUES FOR PRODUCT
11 FEES.—The total fee revenues to be collected in ge-
12 neric new animal drug product fees under subsection
13 (a)(2) shall be \$1,691,000 for fiscal year 2009,
14 \$1,787,000 for fiscal year 2010, \$1,889,000 for fis-
15 cal year 2011, \$1,997,000 for fiscal year 2012, and
16 \$2,111,000 for fiscal year 2013.

17 “(3) TOTAL FEE REVENUES FOR SPONSOR
18 FEES.—The total fee revenues to be collected in ge-
19 neric new animal drug sponsor fees under subsection
20 (a)(3) shall be \$1,691,000 for fiscal year 2009,
21 \$1,787,000 for fiscal year 2010, \$1,889,000 for fis-
22 cal year 2011, \$1,997,000 for fiscal year 2012, and
23 \$2,111,000 for fiscal year 2013.

24 “(c) ADJUSTMENTS.—

1 “(1) WORKLOAD ADJUSTMENT.—The fee reve-
2 nues shall be adjusted each fiscal year after fiscal
3 year 2009 to reflect changes in review workload.

4 With respect to such adjustment:

5 “(A) This adjustment shall be determined
6 by the Secretary based on a weighted average
7 of the change in the total number of abbrevi-
8 ated applications for generic new animal
9 drugs, manufacturing supplemental abbreviated
10 applications for generic new animal drugs, in-
11 vestigational generic new animal drug study
12 submissions, and investigational generic new
13 animal drug protocol submissions submitted to
14 the Secretary. The Secretary shall publish in
15 the Federal Register the fees resulting from
16 this adjustment and the supporting methodolo-
17 gies.

18 “(B) Under no circumstances shall this
19 workload adjustment result in fee revenues for
20 a fiscal year that are less than the fee revenues
21 for that fiscal year established in subsection
22 (b).

23 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
24 year 2013, the Secretary may further increase the
25 fees to provide for up to 3 months of operating re-

1 serves of carryover user fees for the process for the
2 review of abbreviated applications for generic new
3 animal drugs for the first 3 months of fiscal year
4 2014. If the Food and Drug Administration has car-
5 rryover balances for the process for the review of ab-
6 breviated applications for generic new animal drugs
7 in excess of 3 months of such operating reserves,
8 then this adjustment shall not be made. If this ad-
9 justment is necessary, then the rationale for the
10 amount of the increase shall be contained in the an-
11 nual notice setting fees for fiscal year 2013.

12 “(3) ANNUAL FEE SETTING.—The Secretary
13 shall establish, 60 days before the start of each fis-
14 cal year beginning after September 30, 2008, for
15 that fiscal year, abbreviated application fees, generic
16 new animal drug sponsor fees, and generic new ani-
17 mal drug product fees based on the revenue amounts
18 established under subsection (b) and the adjust-
19 ments provided under this subsection.

20 “(4) LIMIT.—The total amount of fees charged,
21 as adjusted under this subsection, for a fiscal year
22 may not exceed the total costs for such fiscal year
23 for the resources allocated for the process for the re-
24 view of abbreviated applications for generic new ani-
25 mal drugs.

1 “(d) FEE WAIVER OR REDUCTION.—The Secretary
2 shall grant a waiver from or a reduction of 1 or more fees
3 assessed under subsection (a) where the Secretary finds
4 that the generic new animal drug is intended solely to pro-
5 vide for a minor use or minor species indication.

6 “(e) EFFECT OF FAILURE TO PAY FEES.—An abbrev-
7 viated application for a generic new animal drug sub-
8 mitted by a person subject to fees under subsection (a)
9 shall be considered incomplete and shall not be accepted
10 for filing by the Secretary until all fees owed by such per-
11 son have been paid. An investigational submission for a
12 generic new animal drug that is submitted by a person
13 subject to fees under subsection (a) shall be considered
14 incomplete and shall not be accepted for review by the Sec-
15 retary until all fees owed by such person have been paid.
16 The Secretary may discontinue review of any abbreviated
17 application for a generic new animal drug, supplemental
18 abbreviated application for a generic new animal drug, or
19 investigational submission for a generic new animal drug
20 from a person if such person has not submitted for pay-
21 ment all fees owed under this section by 30 days after
22 the date upon which they are due.

23 “(f) ASSESSMENT OF FEES.—

24 “(1) LIMITATION.—Fees may not be assessed
25 under subsection (a) for a fiscal year beginning after

1 fiscal year 2008 unless appropriations for salaries
2 and expenses of the Food and Drug Administration
3 for such fiscal year (excluding the amount of fees
4 appropriated for such fiscal year) are equal to or
5 greater than the amount of appropriations for the
6 salaries and expenses of the Food and Drug Admin-
7 istration for the fiscal year 2003 (excluding the
8 amount of fees appropriated for such fiscal year)
9 multiplied by the adjustment factor applicable to the
10 fiscal year involved.

11 “(2) AUTHORITY.—If the Secretary does not
12 assess fees under subsection (a) during any portion
13 of a fiscal year because of paragraph (1) and if at
14 a later date in such fiscal year the Secretary may as-
15 sess such fees, the Secretary may assess and collect
16 such fees, without any modification in the rate, for
17 abbreviated applications, generic new animal drug
18 sponsors, and generic new animal drug products at
19 any time in such fiscal year notwithstanding the pro-
20 visions of subsection (a) relating to the date fees are
21 to be paid.

22 “(g) CREDITING AND AVAILABILITY OF FEES.—

23 “(1) IN GENERAL.—Fees authorized under sub-
24 section (a) shall be collected and available for obliga-
25 tion only to the extent and in the amount provided

1 in advance in appropriations Acts. Such fees are au-
2 thORIZED to be appropriated to remain available until
3 expended. Such sums as may be necessary may be
4 transferred from the Food and Drug Administration
5 salaries and expenses appropriation account without
6 fiscal year limitation to such appropriation account
7 for salary and expenses with such fiscal year limita-
8 tion. The sums transferred shall be available solely
9 for the process for the review of abbreviated applica-
10 tions for generic new animal drugs.

11 “(2) COLLECTIONS AND APPROPRIATION
12 ACTS.—

13 “(A) IN GENERAL.—The fees authorized
14 by this section—

15 “(i) shall be retained in each fiscal
16 year in an amount not to exceed the
17 amount specified in appropriation Acts, or
18 otherwise made available for obligation for
19 such fiscal year; and

20 “(ii) shall only be collected and avail-
21 able to defray increases in the costs of the
22 resources allocated for the process for the
23 review of abbreviated applications for ge-
24 neric new animal drugs (including in-
25 creases in such costs for an additional

1 number of full-time equivalent positions in
2 the Department of Health and Human
3 Services to be engaged in such process)
4 over such costs, excluding costs paid from
5 fees collected under this section, for fiscal
6 year 2008 multiplied by the adjustment
7 factor.

8 “(B) COMPLIANCE.—The Secretary shall
9 be considered to have met the requirements of
10 subparagraph (A)(ii) in any fiscal year if the
11 costs funded by appropriations and allocated for
12 the process for the review of abbreviated appli-
13 cations for generic new animal drugs—

14 “(i) are not more than 3 percent
15 below the level specified in subparagraph
16 (A)(ii); or

17 “(ii)(I) are more than 3 percent below
18 the level specified in subparagraph (A)(ii),
19 and fees assessed for the fiscal year fol-
20 lowing the subsequent fiscal year are de-
21 creased by the amount in excess of 3 per-
22 cent by which such costs fell below the
23 level specified in subparagraph (A)(ii); and

1 “(II) such costs are not more than 5
2 percent below the level specified in sub-
3 paragraph (A)(ii).

4 “(3) AUTHORIZATION OF APPROPRIATIONS.—
5 There are authorized to be appropriated for fees
6 under this section—

7 “(A) \$4,831,000 for fiscal year 2009;

8 “(B) \$5,106,000 for fiscal year 2010;

9 “(C) \$5,397,000 for fiscal year 2011;

10 “(D) \$5,706,000 for fiscal year 2012; and

11 “(E) \$6,031,000 for fiscal year 2013;

12 as adjusted to reflect adjustments in the total fee
13 revenues made under this section and changes in the
14 total amounts collected by abbreviated application
15 fees, generic new animal drug sponsor fees, and ge-
16 neric new animal drug product fees.

17 “(4) OFFSET.—If the sum of the cumulative
18 amount of fees collected under this section for the
19 fiscal years 2009 through 2011 and the amount of
20 fees estimated to be collected under this section for
21 fiscal year 2012 exceeds the cumulative amount ap-
22 propriated under paragraph (3) for the fiscal years
23 2009 through 2012, the excess amount shall be
24 credited to the appropriation account of the Food
25 and Drug Administration as provided in paragraph

1 (1), and shall be subtracted from the amount of fees
2 that would otherwise be authorized to be collected
3 under this section pursuant to appropriation Acts
4 for fiscal year 2013.

5 “(h) COLLECTION OF UNPAID FEES.—In any case
6 where the Secretary does not receive payment of a fee as-
7 sessed under subsection (a) within 30 days after it is due,
8 such fee shall be treated as a claim of the United States
9 Government subject to subchapter II of chapter 37 of title
10 31, United States Code.

11 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
12 TIONS, AND REFUNDS.—To qualify for consideration for
13 a waiver or reduction under subsection (d), or for a refund
14 of any fee collected in accordance with subsection (a), a
15 person shall submit to the Secretary a written request for
16 such waiver, reduction, or refund not later than 180 days
17 after such fee is due.

18 “(j) CONSTRUCTION.—This section may not be con-
19 strued to require that the number of full-time equivalent
20 positions in the Department of Health and Human Serv-
21 ices, for officers, employees, and advisory committees not
22 engaged in the process of the review of abbreviated appli-
23 cations for generic new animal drugs, be reduced to offset
24 the number of officers, employees, and advisory commit-
25 tees so engaged.

1 “(k) DEFINITIONS.—In this section and section 742:

2 “(1) ABBREVIATED APPLICATION FOR A GE-
3 NERIC NEW ANIMAL DRUG.—The terms ‘abbreviated
4 application for a generic new animal drug’ and ‘ab-
5 breviated application’ mean an abbreviated applica-
6 tion for the approval of any generic new animal drug
7 submitted under section 512(b)(2). Such term does
8 not include a supplemental abbreviated application
9 for a generic new animal drug.

10 “(2) ADJUSTMENT FACTOR.—The term ‘adjust-
11 ment factor’ applicable to a fiscal year is the Con-
12 sumer Price Index for all urban consumers (all
13 items; United States city average) for October of the
14 preceding fiscal year divided by—

15 “(A) for purposes of subsection (f)(1),
16 such Index for October 2002; and

17 “(B) for purposes of subsection
18 (g)(2)(A)(ii), such Index for October 2007.

19 “(3) COSTS OF RESOURCES ALLOCATED FOR
20 THE PROCESS FOR THE REVIEW OF ABBREVIATED
21 APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—
22 The term ‘costs of resources allocated for the proc-
23 ess for the review of abbreviated applications for ge-
24 neric new animal drugs’ means the expenses in-
25 curred in connection with the process for the review

1 of abbreviated applications for generic new animal
2 drugs for—

3 “(A) officers and employees of the Food
4 and Drug Administration, contractors of the
5 Food and Drug Administration, advisory com-
6 mittees consulted with respect to the review of
7 specific abbreviated applications, supplemental
8 abbreviated applications, or investigational sub-
9 missions, and costs related to such officers, em-
10 ployees, committees, and contractors, including
11 costs for travel, education, and recruitment and
12 other personnel activities;

13 “(B) management of information, and the
14 acquisition, maintenance, and repair of com-
15 puter resources;

16 “(C) leasing, maintenance, renovation, and
17 repair of facilities and acquisition, maintenance,
18 and repair of fixtures, furniture, scientific
19 equipment, and other necessary materials and
20 supplies; and

21 “(D) collecting fees under this section and
22 accounting for resources allocated for the re-
23 view of abbreviated applications, supplemental
24 abbreviated applications, and investigational
25 submissions.

1 “(4) FINAL DOSAGE FORM.—The term ‘final
2 dosage form’ means, with respect to a generic new
3 animal drug product, a finished dosage form which
4 is approved for administration to an animal without
5 substantial further manufacturing. Such term in-
6 cludes generic new animal drug products intended
7 for mixing in animal feeds.

8 “(5) GENERIC NEW ANIMAL DRUG.—The term
9 ‘generic new animal drug’ means a new animal drug
10 that is the subject of an abbreviated application.

11 “(6) GENERIC NEW ANIMAL DRUG PRODUCT.—
12 The term ‘generic new animal drug product’ means
13 each specific strength or potency of a particular ac-
14 tive ingredient or ingredients in final dosage form
15 marketed by a particular manufacturer or dis-
16 tributor, which is uniquely identified by the labeler
17 code and product code portions of the national drug
18 code, and for which an abbreviated application for a
19 generic new animal drug or a supplemental abbrevi-
20 ated application has been approved.

21 “(7) GENERIC NEW ANIMAL DRUG SPONSOR.—
22 The term ‘generic new animal drug sponsor’ means
23 either an applicant named in an abbreviated applica-
24 tion for a generic new animal drug that has not been
25 withdrawn by the applicant and for which approval

1 has not been withdrawn by the Secretary, or a per-
2 son who has submitted an investigational submission
3 for a generic new animal drug that has not been ter-
4 minated or otherwise rendered inactive by the Sec-
5 retary.

6 “(8) INVESTIGATIONAL SUBMISSION FOR A GE-
7 NERIC NEW ANIMAL DRUG.—The terms ‘investiga-
8 tional submission for a generic new animal drug’
9 and ‘investigational submission’ mean—

10 “(A) the filing of a claim for an investiga-
11 tional exemption under section 512(j) for a ge-
12 neric new animal drug intended to be the sub-
13 ject of an abbreviated application or a supple-
14 mental abbreviated application; or

15 “(B) the submission of information for the
16 purpose of enabling the Secretary to evaluate
17 the safety or effectiveness of a generic new ani-
18 mal drug in the event of the filing of an abbrevi-
19 ated application or supplemental abbreviated
20 application for such drug.

21 “(9) PERSON.—The term ‘person’ includes an
22 affiliate thereof (as such term is defined in section
23 735(11)).

24 “(10) PROCESS FOR THE REVIEW OF ABBRE-
25 VIATED APPLICATIONS FOR GENERIC NEW ANIMAL

1 DRUGS.—The term ‘process for the review of abbrevi-
2 viated applications for generic new animal drugs’
3 means the following activities of the Secretary with
4 respect to the review of abbreviated applications,
5 supplemental abbreviated applications, and inves-
6 tigational submissions:

7 “(A) The activities necessary for the re-
8 view of abbreviated applications, supplemental
9 abbreviated applications, and investigational
10 submissions.

11 “(B) The issuance of action letters which
12 approve abbreviated applications or supple-
13 mental abbreviated applications or which set
14 forth in detail the specific deficiencies in abbrevi-
15 ated applications, supplemental abbreviated
16 applications, or investigational submissions and,
17 where appropriate, the actions necessary to
18 place such applications, supplemental applica-
19 tions, or submissions in condition for approval.

20 “(C) The inspection of generic new animal
21 drug establishments and other facilities under-
22 taken as part of the Secretary’s review of pend-
23 ing abbreviated applications, supplemental ab-
24 breviated applications, and investigational sub-
25 missions.

1 “(D) Monitoring of research conducted in
2 connection with the review of abbreviated appli-
3 cations, supplemental abbreviated applications,
4 and investigational submissions.

5 “(E) The development of regulations and
6 policy related to the review of abbreviated appli-
7 cations, supplemental abbreviated applications,
8 and investigational submissions.

9 “(F) Development of standards for prod-
10 ucts subject to review.

11 “(G) Meetings between the agency and the
12 generic new animal drug sponsor.

13 “(H) Review of advertising and labeling
14 prior to approval of an abbreviated application
15 or supplemental abbreviated application, but
16 not after such application has been approved.

17 “(11) SUPPLEMENTAL ABBREVIATED APPLICA-
18 TION FOR GENERIC NEW ANIMAL DRUG.—The terms
19 ‘supplemental abbreviated application for a generic
20 new animal drug’ and ‘supplemental abbreviated ap-
21 plication’ mean a request to the Secretary to ap-
22 prove a change in an approved abbreviated applica-
23 tion.”.

1 **SEC. 203. ACCOUNTABILITY AND REPORTS.**

2 Part 5 of subchapter C of chapter VII of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.),
4 as added by section 202, is amended by inserting after
5 section 741 the following:

6 **“SEC. 742. REAUTHORIZATION; REPORTING REQUIRE-**
7 **MENTS.**

8 “(a) PERFORMANCE REPORTS.—Beginning with fis-
9 cal year 2009, not later than 60 days after the end of
10 each fiscal year during which fees are collected under this
11 part, the Secretary shall prepare and submit to the Com-
12 mittee on Health, Education, Labor, and Pensions of the
13 Senate, and the Committee on Energy and Commerce of
14 the House of Representatives a report concerning the
15 progress of the Food and Drug Administration in achiev-
16 ing the goals identified in the letters described in section
17 201(3) of the Animal Generic Drug User Fee Act of 2008
18 toward expediting the generic new animal drug develop-
19 ment process and the review of abbreviated applications
20 for generic new animal drugs, supplemental abbreviated
21 applications for generic new animal drugs, and investiga-
22 tional submissions for generic new animal drugs during
23 such fiscal year.

24 “(b) FISCAL REPORT.—Beginning with fiscal year
25 2009, not later than 120 days after the end of each fiscal
26 year during which fees are collected under this part, the

1 Secretary shall prepare and submit to Committee on
2 Health, Education, Labor, and Pensions of the Senate and
3 the Committee on Energy and Commerce of the House
4 of Representatives a report on the implementation of the
5 authority for such fees during such fiscal year and the
6 use, by the Food and Drug Administration, of the fees
7 collected during such fiscal year for which the report is
8 made.

9 “(c) PUBLIC AVAILABILITY.—The Secretary shall
10 make the reports required under subsections (a) and (b)
11 available to the public on the Internet Web site of the
12 Food and Drug Administration.

13 “(d) REAUTHORIZATION.—

14 “(1) CONSULTATION.—In developing rec-
15 ommendations to present to Congress with respect to
16 the goals, and plans for meeting the goals, for the
17 process for the review of abbreviated applications for
18 generic new animal drugs for the first 5 fiscal years
19 after fiscal year 2013, and for the reauthorization of
20 this part for such fiscal years, the Secretary shall
21 consult with—

22 “(A) the Committee on Energy and Com-
23 merce of the House of Representatives;

24 “(B) the Committee on Health, Education,
25 Labor, and Pensions of the Senate;

1 “(C) scientific and academic experts;

2 “(D) veterinary professionals;

3 “(E) representatives of patient and con-
4 sumer advocacy groups; and

5 “(F) the regulated industry.

6 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
7 negotiations with the regulated industry on the reau-
8 thorization of this part, the Secretary shall—

9 “(A) publish a notice in the Federal Reg-
10 ister requesting public input on the reauthoriza-
11 tion;

12 “(B) hold a public meeting at which the
13 public may present its views on the reauthoriza-
14 tion, including specific suggestions for changes
15 to the goals referred to in subsection (a);

16 “(C) provide a period of 30 days after the
17 public meeting to obtain written comments from
18 the public suggesting changes to this part; and

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

21 “(3) PERIODIC CONSULTATION.—Not less fre-
22 quently than once every 4 months during negotia-
23 tions with the regulated industry, the Secretary shall
24 hold discussions with representatives of veterinary,
25 patient, and consumer advocacy groups to continue

1 discussions of their views on the reauthorization and
2 their suggestions for changes to this part as ex-
3 pressed under paragraph (2).

4 “(4) PUBLIC REVIEW OF RECOMMENDA-
5 TIONS.—After negotiations with the regulated indus-
6 try, the Secretary shall—

7 “(A) present the recommendations devel-
8 oped under paragraph (1) to the congressional
9 committees specified in such paragraph;

10 “(B) publish such recommendations in the
11 Federal Register;

12 “(C) provide for a period of 30 days for
13 the public to provide written comments on such
14 recommendations;

15 “(D) hold a meeting at which the public
16 may present its views on such recommenda-
17 tions; and

18 “(E) after consideration of such public
19 views and comments, revise such recommenda-
20 tions as necessary.

21 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
22 Not later than January 15, 2013, the Secretary
23 shall transmit to Congress the revised recommenda-
24 tions under paragraph (4), a summary of the views
25 and comments received under such paragraph, and

1 any changes made to the recommendations in re-
2 sponse to such views and comments.

3 “(6) MINUTES OF NEGOTIATION MEETINGS.—

4 “(A) PUBLIC AVAILABILITY.—Before pre-
5 senting the recommendations developed under
6 paragraphs (1) through (5) to Congress, the
7 Secretary shall make publicly available, on the
8 Internet Web site of the Food and Drug Ad-
9 ministration, minutes of all negotiation meet-
10 ings conducted under this subsection between
11 the Food and Drug Administration and the reg-
12 ulated industry.

13 “(B) CONTENT.—The minutes described
14 under subparagraph (A) shall summarize any
15 substantive proposal made by any party to the
16 negotiations as well as significant controversies
17 or differences of opinion during the negotiations
18 and their resolution.”.

19 **SEC. 204. SUNSET DATES.**

20 (a) AUTHORIZATION.—The amendments made by
21 section 202 shall cease to be effective October 1, 2013.

22 (b) REPORTING REQUIREMENTS.—The amendment
23 made by section 203 shall cease to be effective January
24 31, 2014.

1 **TITLE III—TECHNICAL**
2 **CORRECTIONS TO FDAAA**

3 **SEC. 301. CONSIDERATION OF CERTAIN PETITIONS.**

4 Subparagraph (A) of section 505(q)(1) (21 U.S.C.
5 355(q)(1)) is amended by adding at the end the following:

6 “Consideration of the petition shall be separate
7 and apart from review and approval of any ap-
8 plication.”.

9 **SEC. 302. REGISTRY AND RESULTS DATA BANK.**

10 Paragraph (3) of section 402(j) of the Public Health
11 Service Act (42 U.S.C. 282(j)) is amended—

12 (1) in the matter preceding clause (i) in sub-
13 paragraph (C), by striking “the following elements”
14 and all that follows through “520(m) of such Act:”
15 and inserting “for each applicable clinical trial for a
16 drug that is approved under section 505 of the Fed-
17 eral Food, Drug, and Cosmetic Act or licensed under
18 section 351 of this Act or a device that is cleared
19 under section 510(k) of the Federal Food, Drug,
20 and Cosmetic Act or approved under section 515 or
21 520(m) of such Act, the following elements:”; and

22 (2) in clauses (i) and (iii) of subparagraph (I),
23 by striking the term “drugs described in subpara-
24 graph (C)” each place such term appears and insert-

1 ing “applicable clinical trials described in subpara-
2 graph (C)”.

Passed the House of Representatives July 30, 2008.

Attest:

Clerk.

110TH CONGRESS
2^D SESSION

H. R. 6432

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.