

110TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, 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. SHORT TITLE; REFERENCES; FINDING.**

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

6 (b) REFERENCES IN ACT.—Except as otherwise spec-  
7 ified, amendments made by this Act to a section or other  
8 provision of law are amendments to such section or other  
9 provision of the Federal Food, Drug, and Cosmetic Act  
10 (21 U.S.C. 301 et seq.).

1 (c) FINDING.—Congress finds that the fees author-  
2 ized by the amendments made in this Act will be dedicated  
3 toward expediting the animal drug development process  
4 and the review of new and supplemental animal drug ap-  
5 plications and investigational animal drug submissions as  
6 set forth in the goals identified, for purposes of part 4  
7 of subchapter C of chapter VII of the Federal Food, Drug,  
8 and Cosmetic Act, in the letters from the Secretary of  
9 Health and Human Services to the Chairman of the Com-  
10 mittee on Energy and Commerce of the House of Rep-  
11 resentatives 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. 2. 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19 510” and inserting “that has not been withdrawn”;

20 (2) in paragraph (10), by striking “year being  
21 2003” and inserting “month being October 2002”;

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

24 (4) by inserting after paragraph (10) the fol-  
25 lowing:

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

3 **SEC. 3. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
4 **FEEES.**

5           (a) TYPES OF FEES.—Section 740(a) (21 U.S.C.  
6 379j–12(a)) is amended—

7           (1) in paragraph (1)(A)(i), by inserting after  
8           “for an animal drug application” the following: “,  
9           except an animal drug application subject to the cri-  
10          teria set forth in section 512(d)(4)”; and

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

13                   “(ii) A fee established in subsection  
14                   (b), in an amount that is equal to 50 per-  
15                   cent of the amount of the fee under clause  
16                   (i), for—

17                           “(I) a supplemental animal drug  
18                           application for which safety or effec-  
19                           tiveness data are required; and

20                                   “(II) an animal drug application  
21                                   subject to the criteria set forth in sec-  
22                                   tion 512(d)(4).”.

23          (b) FEE AMOUNTS.—

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

4                   (A) by striking “and supplemental animal  
5                   drug application fees” and inserting “and sup-  
6                   plemental and other animal drug application  
7                   fees”; and

8                   (B) by striking “\$1,250,000” and all that  
9                   follows through the period at the end and in-  
10                  serting “\$3,815,000 in fiscal year 2009,  
11                  \$4,320,000 in fiscal year 2010, \$4,862,000 in  
12                  fiscal year 2011, \$5,442,000 in fiscal year  
13                  2012, and \$6,061,000 in fiscal year 2013.”.

14           (2) TOTAL FEE REVENUES FOR PRODUCT  
15           FEES.—Section 740(b)(2) (21 U.S.C. 379j–  
16           12(b)(2)) is amended by striking “\$1,250,000” and  
17           all that follows through the period at the end and  
18           inserting “\$3,815,000 for fiscal year 2009,  
19           \$4,320,000 for fiscal year 2010, \$4,862,000 for fis-  
20           cal year 2011, \$5,442,000 for fiscal year 2012, and  
21           \$6,061,000 for fiscal year 2013.”.

22           (3) TOTAL FEE REVENUES FOR ESTABLISH-  
23           MENT FEES.—Section 740(b)(3) (21 U.S.C. 379j–  
24           12(b)(3)) is amended by striking “\$1,250,000” and  
25           all that follows through the period at the end and

1 inserting “\$3,815,000 for fiscal year 2009,  
2 \$4,320,000 for fiscal year 2010, \$4,862,000 for fis-  
3 cal year 2011, \$5,442,000 for fiscal year 2012, and  
4 \$6,061,000 for fiscal year 2013.”.

5 (4) TOTAL FEE REVENUES FOR SPONSOR  
6 FEES.—Section 740(b)(4) (21 U.S.C. 379j–  
7 12(b)(4)) is amended by striking “\$1,250,000” and  
8 all that follows through the period at the end and  
9 inserting “\$3,815,000 for fiscal year 2009,  
10 \$4,320,000 for fiscal year 2010, \$4,862,000 for fis-  
11 cal year 2011, \$5,442,000 for fiscal year 2012, and  
12 \$6,061,000 for fiscal year 2013.”.

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

15 (1) by striking paragraph (1);

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

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

19 (A) in the matter preceding subparagraph  
20 (A), by striking “After the fee revenues are ad-  
21 justed for inflation in accordance with para-  
22 graph (1), the fee revenues shall be further ad-  
23 justed each fiscal year after fiscal year 2004”  
24 and inserting “The fee revenues shall be ad-

1           justed each fiscal year after fiscal year 2009”;

2           and

3                   (B) in subparagraph (B), by striking “, as

4           adjusted for inflation under paragraph (1)”;

5           and

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

7                   (A) by striking “2008” each place it ap-

8           pears and inserting “2013”; and

9                   (B) by striking “2009” and inserting

10          “2014”.

11          (d) **AUTHORIZATION OF APPROPRIATIONS.**—Sub-

12         paragraphs (A) through (E) of section 740(g)(3) (21

13         U.S.C. 379j–12(g)(3)) are amended to read as follows:

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

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

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

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

18           and

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

20          (e) **OFFSET.**—Section 740(g)(4) (21 U.S.C. 379j–

21         12(g)(4)) is amended to read as follows:

22                   “(4) **OFFSET.**—If the sum of the cumulative

23         amount of fees collected under this section for fiscal

24         years 2009 through 2011 and the amount of fees es-

25         timated to be collected under this section for fiscal

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

10 **SEC. 4. REAUTHORIZATION; REPORTING REQUIREMENTS.**

11 Part 4 of subchapter C of chapter VII (21 U.S.C.  
12 379j–11 et seq.) is amended by inserting after section 740  
13 the following:

14 **“SEC. 740A. REAUTHORIZATION; REPORTING REQUIRE-**  
15 **MENTS.**

16 “(a) PERFORMANCE REPORT.—Beginning with fiscal  
17 year 2009, not later than 60 days after the end of each  
18 fiscal year during which fees are collected under this part,  
19 the Secretary shall prepare and submit to the Committee  
20 on Energy and Commerce of the House of Representatives  
21 and the Committee on Health, Education, Labor, and  
22 Pensions of the Senate a report concerning the progress  
23 of the Food and Drug Administration in achieving the  
24 goals identified in the letters described in section 1(c) of  
25 the Animal Drug User Fee Amendments of 2008 toward

1 expediting the animal drug development process and the  
2 review of the new and supplemental animal drug applica-  
3 tions and investigational animal drug submissions during  
4 such fiscal year, the future plans of the Food and Drug  
5 Administration for meeting the goals, the review times for  
6 abbreviated new animal drug applications, and the admin-  
7 istrative procedures adopted by the Food and Drug Ad-  
8 ministration to ensure that review times for abbreviated  
9 new animal drug applications are not increased from their  
10 current level due to activities under the user fee program.

11       “(b) FISCAL REPORT.—Beginning with fiscal year  
12 2009, not later than 120 days after the end of each fiscal  
13 year during which fees are collected under this part, the  
14 Secretary shall prepare and submit to the Committee on  
15 Energy and Commerce of the House of Representatives  
16 and the Committee on Health, Education, Labor, and  
17 Pensions of the Senate a report on the implementation  
18 of the authority for such fees during such fiscal year and  
19 the use, by the Food and Drug Administration, of the fees  
20 collected during such fiscal year for which the report is  
21 made.

22       “(c) PUBLIC AVAILABILITY.—The Secretary shall  
23 make the reports required under subsections (a) and (b)  
24 available to the public on the Internet Web site of the  
25 Food and Drug Administration.



1 “(d) REAUTHORIZATION.—

2 “(1) CONSULTATION.—In developing rec-  
3 ommendations to present to the Congress with re-  
4 spect to the goals, and plans for meeting the goals,  
5 for the process for the review of animal drug appli-  
6 cations for the first 5 fiscal years after fiscal year  
7 2013, and for the reauthorization of this part for  
8 such fiscal years, the Secretary shall consult with—

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

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

13 “(C) scientific and academic experts;

14 “(D) veterinary professionals;

15 “(E) representatives of patient and con-  
16 sumer advocacy groups; and

17 “(F) the regulated industry.

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

21 “(A) publish a notice in the Federal Reg-  
22 ister requesting public input on the reauthoriza-  
23 tion;

24 “(B) hold a public meeting at which the  
25 public may present its views on the reauthoriza-

1           tion, including specific suggestions for changes  
2           to the goals referred to in subsection (a);

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

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

8           “(3) PERIODIC CONSULTATION.—Not less fre-  
9           quently than once every month during negotiations  
10          with the regulated industry, the Secretary shall hold  
11          discussions with representatives of patient and con-  
12          sumer advocacy groups to continue discussions of  
13          their views on the reauthorization and their sugges-  
14          tions for changes to this part as expressed under  
15          paragraph (2).

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

19                 “(A) present the recommendations devel-  
20                 oped under paragraph (1) to the Congressional  
21                 committees specified in such paragraph;

22                 “(B) publish such recommendations in the  
23                 Federal Register;

1           “(C) provide for a period of 30 days for  
2           the public to provide written comments on such  
3           recommendations;

4           “(D) hold a meeting at which the public  
5           may present its views on such recommenda-  
6           tions; and

7           “(E) after consideration of such public  
8           views and comments, revise such recommenda-  
9           tions as necessary.

10          “(5) TRANSMITTAL OF RECOMMENDATIONS.—  
11          Not later than January 15, 2013, the Secretary  
12          shall transmit to the Congress the revised rec-  
13          ommendations under paragraph (4), a summary of  
14          the views and comments received under such para-  
15          graph, and any changes made to the recommenda-  
16          tions in response to such views and comments.

17          “(6) MINUTES OF NEGOTIATION MEETINGS.—

18                 “(A) PUBLIC AVAILABILITY.—Before pre-  
19                 senting the recommendations developed under  
20                 paragraphs (1) through (5) to the Congress, the  
21                 Secretary shall make publicly available, on the  
22                 Internet Web site of the Food and Drug Ad-  
23                 ministration, minutes of all negotiation meet-  
24                 ings conducted under this subsection between

1 the Food and Drug Administration and the reg-  
2 ulated industry.

3 “(B) CONTENT.—The minutes described  
4 under subparagraph (A) shall summarize any  
5 substantive proposal made by any party to the  
6 negotiations as well as significant controversies  
7 or differences of opinion during the negotiations  
8 and their resolution.”.

9 **SEC. 5. PERIODIC DRUG EXPERIENCE REPORTS.**

10 (a) REPORTING PERIOD; SUBMISSION DATE.—With  
11 respect to periodic drug experience reports on antibiotic  
12 new animal drugs that are required under section  
13 514.80(b)(4) of title 21, Code of Federal Regulations, the  
14 Secretary of Health and Human Services (in this section  
15 referred to as the “Secretary”) shall modify such section  
16 to provide that, in the case of each such report that is  
17 required on an annual basis—

18 (1) the reporting period is the calendar year,  
19 beginning with calendar year 2008; and

20 (2) the report on such a period is due not later  
21 than March 31 following the end of the period.

22 (b) TRANSITIONAL PROVISION.—

23 (1) IN GENERAL.—With respect to periodic  
24 drug experience reports under section 514.80(b)(4)  
25 of title 21, Code of Federal Regulations, that, but

1 for the enactment of this Act, would be due during  
2 the transitional period, the Secretary shall ensure  
3 that implementation of this section does not result  
4 in—

5 (A) excluding any portion of calendar year  
6 2007 from consideration; or

7 (B) delaying the submission date so that a  
8 gap of more than 12 months occurs between the  
9 submission of such reports.

10 (2) DEFINITION.—In this subsection, the term  
11 “transitional period” means the period beginning on  
12 the effective date of the final regulation published  
13 pursuant to subsection (c) and ending on March 30,  
14 2009.

15 (c) RULEMAKING PROCEDURE.—To carry out this  
16 section, the Secretary shall publish a final regulation not  
17 later than 60 days after the date of the enactment of this  
18 Act. For purposes of such rulemaking, good cause (as such  
19 term is used in section 553(b) of title 5, United States  
20 Code) shall be considered to exist.

21 **SEC. 6. SAVINGS CLAUSE.**

22 Notwithstanding section 5 of the Animal Drug User  
23 Fee Act of 2003 (21 U.S.C. 379j–11 note), and notwith-  
24 standing the amendments made by this Act, part 4 of sub-  
25 chapter C of chapter VII of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in effect on  
2 the day before the date of the enactment of this Act, shall  
3 continue to be in effect with respect to animal drug appli-  
4 cations and supplemental animal drug applications (as de-  
5 fined in such part as of such day) that on or after Sep-  
6 tember 1, 2003, but before October 1, 2008, were accepted  
7 by the Food and Drug Administration for filing with re-  
8 spect to assessing and collecting any fee required by such  
9 part for a fiscal year prior to fiscal year 2009.

10 **SEC. 7. EFFECTIVE DATE.**

11 The amendments made by sections 2, 3, and 4 shall  
12 take effect on October 1, 2008, or the date of the enact-  
13 ment of this Act, whichever is later, except that fees under  
14 part 4 of subchapter C of chapter VII of the Federal Food,  
15 Drug, and Cosmetic Act, as amended by this Act, shall  
16 be assessed for all animal drug applications and supple-  
17 mental animal drug applications received on or after Octo-  
18 ber 1, 2008, regardless of the date of the enactment of  
19 this Act.

20 **SEC. 8. SUNSET DATES.**

21 (a) **AUTHORIZATION.**—The amendments made by  
22 sections 2 and 3 cease to be effective October 1, 2013.

23 (b) **REPORTING REQUIREMENTS.**—The amendment  
24 made by section 4 ceases to be effective January 31, 2014.