

# Union Calendar No. 520

110<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6432

[Report No. 110-804]

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

JULY 8, 2008

Mr. PALLONE (for himself, Mr. DINGELL, Mr. BARTON of Texas, Mr. DEAL of Georgia, and Mr. TOWNS) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY 30, 2008

Additional sponsor: Ms. DEGETTE

JULY 30, 2008

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on July 8, 2008]

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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,*

1 **SECTION 1. SHORT TITLE; REFERENCES; FINDING.**

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

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

9 (c) *FINDING.*—*Congress finds that the fees authorized*  
10 *by the amendments made in this Act will be dedicated to-*  
11 *ward expediting the animal drug development process and*  
12 *the review of new and supplemental animal drug applica-*  
13 *tions and investigational animal drug submissions as set*  
14 *forth in the goals identified, for purposes of part 4 of sub-*  
15 *chapter C of chapter VII of the Federal Food, Drug, and*  
16 *Cosmetic Act, in the letters from the Secretary of Health*  
17 *and Human Services to the Chairman of the Committee on*  
18 *Energy and Commerce of the House of Representatives and*  
19 *the Chairman of the Committee on Health, Education,*  
20 *Labor, and Pensions of the Senate as set forth in the Con-*  
21 *gressional Record.*

22 **SEC. 2. DEFINITIONS.**

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

24 (1) *in paragraph (6), by striking “, except for*  
25 *an approved application for which all subject prod-*  
26 *ucts have been removed from listing under section*

1       510” and inserting “that has not been withdrawn by  
2       the applicant and for which approval has not been  
3       withdrawn by the Secretary”;

4               (2) in paragraph (8)(H), by striking “but not  
5       such activities after an animal drug has been ap-  
6       proved” and inserting “but not after such application  
7       has been approved”;

8               (3) in paragraph (10), by striking “year being  
9       2003” and inserting “month being October 2002”;

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

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

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

16 **SEC. 3. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
17 **FEES.**

18       (a) *TYPES OF FEES.*—Section 740(a) (21 U.S.C. 379j–  
19 12(a)) is amended—

20              (1) in paragraph (1)(A)(i), by inserting after  
21       “for an animal drug application” the following: “, ex-  
22       cept an animal drug application subject to the cri-  
23       teria set forth in section 512(d)(4)”;

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

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

4                   “(I) a supplemental animal drug  
5                   application for which safety or effec-  
6                   tiveness data are required; and

7                   “(II) an animal drug application  
8                   subject to the criteria set forth in sec-  
9                   tion 512(d)(4).”.

10       (b) *FEE AMOUNTS.*—

11           (1) *TOTAL FEE REVENUES FOR APPLICATION AND*  
12       *SUPPLEMENT FEES.*—Section 740(b)(1) (21 U.S.C.  
13       379j–12(b)(1)) is amended—

14                   (A) by striking “and supplemental animal  
15                   drug application fees” and inserting “and sup-  
16                   plemental and other animal drug application  
17                   fees”; and

18                   (B) by striking “\$1,250,000” and all that  
19                   follows through the period at the end and insert-  
20                   ing “\$3,815,000 for fiscal year 2009, \$4,320,000  
21                   for fiscal year 2010, \$4,862,000 for fiscal year  
22                   2011, \$5,442,000 for fiscal year 2012, and  
23                   \$6,061,000 for fiscal year 2013.”.

24           (2) *TOTAL FEE REVENUES FOR PRODUCT*  
25       *FEES.*—Section 740(b)(2) (21 U.S.C. 379j–12(b)(2))

1 *is amended by striking “\$1,250,000” and all that fol-*  
2 *lows through the period at the end and inserting*  
3 *“\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal*  
4 *year 2010, \$4,862,000 for fiscal year 2011,*  
5 *\$5,442,000 for fiscal year 2012, and \$6,061,000 for*  
6 *fiscal year 2013.”.*

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

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

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

25 (1) *by striking paragraph (1);*

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

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

4           (A) in the matter preceding subparagraph  
5           (A), by striking “After the fee revenues are ad-  
6           justed for inflation in accordance with para-  
7           graph (1), the fee revenues shall be further ad-  
8           justed each fiscal year after fiscal year 2004”  
9           and inserting “The fee revenues shall be adjusted  
10          each fiscal year after fiscal year 2009”; and

11          (B) in subparagraph (B), by striking “, as  
12          adjusted for inflation under paragraph (1)”; and  
13          (4) in paragraph (2), as so redesignated—

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

16          (B) by striking “2009” and inserting  
17          “2014”.

18          (d) *AUTHORIZATION OF APPROPRIATIONS.*—Subpara-  
19          graphs (A) through (E) of section 740(g)(3) (21 U.S.C.  
20          379j–12(g)(3)) are amended to read as follows:

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

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

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

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

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

1       (e) *OFFSET.*—Section 740(g)(4) (21 U.S.C. 379j–  
2 12(g)(4)) is amended to read as follows:

3           “(4) *OFFSET.*—If the sum of the cumulative  
4 amount of fees collected under this section for fiscal  
5 years 2009 through 2011 and the amount of fees esti-  
6 mated to be collected under this section for fiscal year  
7 2012 exceeds the cumulative amount appropriated  
8 under paragraph (3) for the fiscal years 2009 through  
9 2012, the excess amount shall be credited to the ap-  
10 propriation account of the Food and Drug Adminis-  
11 tration as provided in paragraph (1), and shall be  
12 subtracted from the amount of fees that would other-  
13 wise be authorized to be collected under this section  
14 pursuant to appropriation Acts for fiscal year 2013.”.

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

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

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

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

1 *the Committee on Health, Education, Labor, and Pensions*  
2 *of the Senate a report concerning the progress of the Food*  
3 *and Drug Administration in achieving the goals identified*  
4 *in the letters described in section 1(c) of the Animal Drug*  
5 *User Fee Amendments of 2008 toward expediting the ani-*  
6 *mal drug development process and the review of the new*  
7 *and supplemental animal drug applications and investiga-*  
8 *tional animal drug submissions during such fiscal year, the*  
9 *future plans of the Food and Drug Administration for meet-*  
10 *ing the goals, the review times for abbreviated new animal*  
11 *drug applications, and the administrative procedures*  
12 *adopted by the Food and Drug Administration to ensure*  
13 *that review times for abbreviated new animal drug applica-*  
14 *tions are not increased from their current level due to ac-*  
15 *tivities under the user 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 and*  
21 *the Committee on Health, Education, Labor, and Pensions*  
22 *of the Senate a report on the implementation of the author-*  
23 *ity for such fees during such fiscal year and the use, by*  
24 *the Food and Drug Administration, of the fees collected dur-*  
25 *ing such fiscal year for which the report is made.*

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

5       “(d) *REAUTHORIZATION.*—

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

13                   “(A) *the Committee on Energy and Com-*  
14 *merce of the House of Representatives;*

15                   “(B) *the Committee on Health, Education,*  
16 *Labor, and Pensions of the Senate;*

17                   “(C) *scientific and academic experts;*

18                   “(D) *veterinary professionals;*

19                   “(E) *representatives of patient and con-*  
20 *sumer advocacy groups; and*

21                   “(F) *the regulated industry.*

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

1           “(A) publish a notice in the *Federal Reg-*  
2           *ister requesting public input on the reauthoriza-*  
3           *tion;*

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

8           “(C) provide a period of 30 days after the  
9           *public meeting to obtain written comments from*  
10          *the public suggesting changes to this part; and*

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

13          “(3) *PERIODIC CONSULTATION.*—Not less fre-  
14          *quently than once every 4 months during negotiations*  
15          *with the regulated industry, the Secretary shall hold*  
16          *discussions with representatives of veterinary, patient,*  
17          *and consumer advocacy groups to continue discus-*  
18          *sions of their views on the reauthorization and their*  
19          *suggestions for changes to this part as expressed*  
20          *under paragraph (2).*

21          “(4) *PUBLIC REVIEW OF RECOMMENDATIONS.*—  
22          *After negotiations with the regulated industry, the*  
23          *Secretary shall—*

1           “(A) present the recommendations developed  
2 under paragraph (1) to the Congressional com-  
3 mittees specified in such paragraph;

4           “(B) publish such recommendations in the  
5 Federal Register;

6           “(C) provide for a period of 30 days for the  
7 public to provide written comments on such rec-  
8 ommendations;

9           “(D) hold a meeting at which the public  
10 may present its views on such recommendations;  
11 and

12           “(E) after consideration of such public  
13 views and comments, revise such recommenda-  
14 tions as necessary.

15           “(5) TRANSMITTAL OF RECOMMENDATIONS.—Not  
16 later than January 15, 2013, the Secretary shall  
17 transmit to the Congress the revised recommendations  
18 under paragraph (4), a summary of the views and  
19 comments received under such paragraph, and any  
20 changes made to the recommendations in response to  
21 such views and comments.

22           “(6) MINUTES OF NEGOTIATION MEETINGS.—

23           “(A) PUBLIC AVAILABILITY.—Before pre-  
24 senting the recommendations developed under  
25 paragraphs (1) through (5) to the Congress, the

1            *Secretary shall make publicly available, on the*  
2            *Internet Web site of the Food and Drug Admin-*  
3            *istration, minutes of all negotiation meetings*  
4            *conducted under this subsection between the Food*  
5            *and Drug Administration and the regulated in-*  
6            *dustry.*

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

13 **SEC. 5. ANTIMICROBIAL ANIMAL DRUG DISTRIBUTION RE-**  
14            **PORTS.**

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

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

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

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

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

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

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

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

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

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

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

19           “(E) The Secretary shall make summaries of the infor-  
20 mation reported under this paragraph publicly available,  
21 except that—

22           “(i) the summary data shall be reported by anti-  
23 microbial class, and no class with fewer than 3 dis-  
24 tinct sponsors of approved applications shall be inde-  
25 pendently reported; and

1           “(ii) the data shall be reported in a manner con-  
2           sistent with protecting both national security and  
3           confidential business information.”.

4           (b) *FIRST REPORT.*—For each new animal drug that  
5 is subject to the reporting requirement under section  
6 512(l)(3) of the Federal Food, Drug, and Cosmetic Act, as  
7 added by subsection (a), and for which an approval of an  
8 application filed pursuant to section 512(b) or 571 of such  
9 Act is in effect on the date of the enactment of this Act,  
10 the Secretary of Health and Human Services shall require  
11 the sponsor of the drug to submit the first report under such  
12 section 512(l)(3) for the drug not later than March 31,  
13 2010.

14           (c) *SEPARATE REPORT.*—The reports required under  
15 section 512(l)(3) of the Federal Food, Drug, and Cosmetic  
16 Act, as added by subsection (a), shall be separate from peri-  
17 odic drug experience reports that are required under section  
18 514.80(b)(4) of title 21, Code of Federal Regulations (as in  
19 effect on the date of the enactment of this Act).

20 **SEC. 6. DESTRUCTION OF COUNTERFEIT ANIMAL DRUGS**  
21 **OFFERED FOR IMPORT.**

22           Section 801(a) (21 U.S.C. 381(a)) is amended—

23           (1) in the third sentence, by inserting “or (4)  
24           such article is a counterfeit drug intended for use for

1       *animals other than man,*” before “*then such article*  
2       *shall be refused admission*”; and

3               (2) by striking “*Clause (2) of the third sentence*  
4       *of this paragraph*” and inserting “*Notwithstanding*  
5       *the preceding sentence, the Secretary of the Treasury*  
6       *shall cause the destruction of any such article refused*  
7       *admission if (1) the article is a drug intended for use*  
8       *for animals other than man, the article appears to be*  
9       *adulterated, misbranded, or in violation of section*  
10       *505, and the article has a value less than \$2,000 or*  
11       *such amount as the Secretary of Health and Human*  
12       *Services may determine by regulation; or (2) the arti-*  
13       *cle appears to be a counterfeit drug intended for use*  
14       *for animals other than man. Clause (2) of the third*  
15       *sentence of this subsection*”.

16   **SEC. 7. SAVINGS CLAUSE.**

17       *Notwithstanding section 5 of the Animal Drug User*  
18       *Fee Act of 2003 (21 U.S.C. 379j–11 note), and notwith-*  
19       *standing the amendments made by this Act, part 4 of sub-*  
20       *chapter C of chapter VII of the Federal Food, Drug, and*  
21       *Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in effect on*  
22       *the day before the date of the enactment of this Act, shall*  
23       *continue to be in effect with respect to animal drug applica-*  
24       *tions and supplemental animal drug applications (as de-*  
25       *finied in such part as of such day) that on or after Sep-*

1 tember 1, 2003, but before October 1, 2008, were accepted  
2 by the Food and Drug Administration for filing with re-  
3 spect to assessing and collecting any fee required by such  
4 part for a fiscal year prior to fiscal year 2009.

5 **SEC. 8. EFFECTIVE DATE.**

6       The amendments made by sections 2, 3, and 4 shall  
7 take effect on October 1, 2008, and fees under part 4 of  
8 subchapter C of chapter VII of the Federal Food, Drug, and  
9 Cosmetic Act, as amended by this Act, shall be assessed for  
10 all animal drug applications and supplemental animal  
11 drug applications received on or after such date, regardless  
12 of the date of the enactment of this Act.

13 **SEC. 9. SUNSET DATES.**

14       (a) *AUTHORIZATION.*—The amendments made by sec-  
15 tions 2 and 3 cease to be effective October 1, 2013.

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



Union Calendar No. 520

110<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H. R. 6432**

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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.

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JULY 30, 2008

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed