

110TH CONGRESS
2D SESSION

H. R. 6433

To amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to generic new animal drugs.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to generic new animal drugs.

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.**

4 (a) SHORT TITLE.—This title may be cited as the
5 “Animal Generic Drug User Fee Act 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 **SEC. 2. FINDINGS.**

2 Congress finds as follows:

3 (1) Prompt approval of abbreviated applications
4 for safe and effective generic new animal drugs will
5 reduce animal healthcare costs and promote the well-
6 being of animal health and the public health.

7 (2) Animal health and the public health will be
8 served by making additional funds available for the
9 purpose of augmenting the resources of the Food
10 and Drug Administration that are devoted to the
11 process for the review of abbreviated applications for
12 the approval of generic new animal drugs.

13 (3) The fees authorized by this title will be
14 dedicated toward expediting the generic new animal
15 drug development process and the review of abbrevi-
16 ated applications for generic new animal drugs,
17 supplemental abbreviated applications for generic
18 new animal drugs, and investigational submissions
19 for generic new animal drugs as set forth in the
20 goals identified in the letters from the Secretary of
21 Health and Human Services to the Chairman of the
22 Committee on Energy and Commerce of the House
23 of Representatives and the Chairman of the Com-
24 mittee on Health, Education, Labor, and Pensions
25 of the Senate as set forth in the Congressional
26 Record.

1 **SEC. 3. FEES RELATING TO ABBREVIATED APPLICATIONS**
2 **FOR GENERIC NEW ANIMAL DRUGS.**

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

6 (b) AUTHORITY TO ASSESS AND USE GENERIC NEW
7 ANIMAL DRUG FEES.—Subchapter C of chapter VII of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 379f et seq.) is amended by adding at the end the fol-
10 lowing:

11 **“PART 5—FEES RELATING TO GENERIC NEW**
12 **ANIMAL DRUGS**

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

15 “(a) TYPES OF FEES.—Beginning with respect to fis-
16 cal year 2009, the Secretary shall assess and collect fees
17 in accordance with this section as follows:

18 “(1) ABBREVIATED APPLICATION FEE.—

19 “(A) IN GENERAL.—Each person that sub-
20 mits, on or after July 1, 2008, an abbreviated
21 application for a generic new animal drug shall
22 be subject to a fee as established in subsection
23 (b) for such an application.

24 “(B) PAYMENT.—The fee required by sub-
25 paragraph (A) shall be due upon submission of
26 the abbreviated application.

1 “(C) EXCEPTION FOR PREVIOUSLY FILED
2 APPLICATION.—If an abbreviated application
3 was submitted by a person that paid the fee for
4 such application, was accepted for filing, and
5 was not approved or was withdrawn (without a
6 waiver or refund), the submission of an abbrevi-
7 ated application for the same product by the
8 same person (or the person’s licensee, assignee,
9 or successor) shall not be subject to a fee under
10 subparagraph (A).

11 “(D) REFUND OF FEE IF APPLICATION RE-
12 FUSED FOR FILING.—The Secretary shall re-
13 fund 75 percent of the fee paid under subpara-
14 graph (B) for any abbreviated application which
15 is refused for filing.

16 “(E) REFUND OF FEE IF APPLICATION
17 WITHDRAWN.—If an abbreviated application is
18 withdrawn after the application was filed, the
19 Secretary may refund the fee or portion of the
20 fee paid under subparagraph (B) if no substan-
21 tial work was performed on the application
22 after the application was filed. The Secretary
23 shall have the sole discretion to refund the fee
24 under this subparagraph. A determination by

1 the Secretary concerning a refund under this
2 subparagraph shall not be reviewable.

3 “(2) GENERIC NEW ANIMAL DRUG PRODUCT
4 FEE.—Each person—

5 “(A) who is named as the applicant in an
6 abbreviated application or supplemental abbrevi-
7 ated application for a generic new animal
8 drug product which has been submitted for list-
9 ing under section 510, and

10 “(B) who, after September 1, 2008, had
11 pending before the Secretary an abbreviated ap-
12 plication or supplemental abbreviated applica-
13 tion,

14 shall pay for each such generic new animal drug
15 product the annual fee established in subsection (b).
16 Such fee shall be payable for the fiscal year in which
17 the generic new animal drug product is first sub-
18 mitted for listing under section 510, or is submitted
19 for relisting under section 510 if the generic new
20 animal drug product has been withdrawn from list-
21 ing and relisted. After such fee is paid for that fiscal
22 year, such fee shall be payable on or before January
23 31 of each year. Such fee shall be paid only once for
24 each generic new animal drug product for a fiscal
25 year in which the fee is payable.

1 “(3) GENERIC NEW ANIMAL DRUG SPONSOR
2 FEE.—

3 “(A) IN GENERAL.—Each person—

4 “(i) who meets the definition of a ge-
5 neric new animal drug sponsor within a
6 fiscal year, and

7 “(ii) who, after September 1, 2008,
8 had pending before the Secretary an abbre-
9 viated application, a supplemental abbre-
10 viated application, or an investigational
11 submission,

12 shall be assessed an annual fee established
13 under subsection (b). The fee shall be paid on
14 or before January 31 of each year.

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

18 “(i) 100 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 more than 6
22 approved abbreviated applications.

23 “(ii) 75 percent of the amount of the
24 generic new animal drug sponsor fee pub-
25 lished for that fiscal year under subsection

1 (c)(3) for an applicant with more than 1
2 and fewer than 7 approved abbreviated ap-
3 plications.

4 “(iii) 50 percent of the amount of the
5 generic new animal drug sponsor fee pub-
6 lished for that fiscal year under subsection
7 (c)(3) for an applicant with 1 or fewer ap-
8 proved abbreviated applications.

9 “(b) FEE AMOUNTS.—Except as provided in sub-
10 section (a)(1) and subsections (c), (d), (f), and (g), the
11 fees required under subsection (a) shall be established to
12 generate fee revenue amounts as follows:

13 “(1) TOTAL FEE REVENUES FOR APPLICATION
14 FEES.—The total fee revenues to be collected in ab-
15 breviated application fees under subsection (a)(1)
16 shall be \$1,449,000 for fiscal year 2009, \$1,532,000
17 for fiscal year 2010, \$1,619,000 for fiscal year
18 2011, \$1,712,000 for fiscal year 2012, and
19 \$1,809,000 for fiscal year 2013.

20 “(2) TOTAL FEE REVENUES FOR PRODUCT
21 FEES.—The total fee revenues to be collected in ge-
22 neric new animal drug product fees under subsection
23 (a)(2) shall be \$1,691,000 for fiscal year 2009,
24 \$1,787,000 for fiscal year 2010, \$1,889,000 for fis-

1 cal year 2011, \$1,997,000 for fiscal year 2012, and
2 \$2,111,000 for fiscal year 2013.

3 “(3) TOTAL FEE REVENUES FOR SPONSOR
4 FEES.—The total fee revenues to be collected in ge-
5 neric new animal drug sponsor fees under subsection
6 (a)(3) shall be \$1,691,000 for fiscal year 2009,
7 \$1,787,000 for fiscal year 2010, \$1,889,000 for fis-
8 cal year 2011, \$1, 997,000 for fiscal year 2012, and
9 \$2,111,000 for fiscal year 2013.

10 “(c) ADJUSTMENTS.—

11 “(1) WORKLOAD ADJUSTMENT.—The fee reve-
12 nues shall be adjusted each fiscal year after fiscal
13 year 2009 to reflect changes in review workload.
14 With respect to such adjustment:

15 “(A) This adjustment shall be determined
16 by the Secretary based on a weighted average
17 of the change in the total number of abbrevi-
18 ated applications for generic new animal
19 drugs, manufacturing supplemental abbreviated
20 applications for generic new animal drugs, in-
21 vestigational new animal drug study submis-
22 sions, and generic investigational new animal
23 drug protocol submissions submitted to the Sec-
24 retary. The Secretary shall publish in the Fed-

1 eral Register the fees resulting from this ad-
2 justment and the supporting methodologies.

3 “(B) Under no circumstances shall this
4 workload adjustment result in fee revenues for
5 a fiscal year that are less than the fee revenues
6 for that fiscal year established in subsection
7 (b).

8 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
9 year 2013, the Secretary may further increase the
10 fees to provide for up to 3 months of operating re-
11 serves of carryover user fees for the process for the
12 review of abbreviated applications for generic new
13 animal drugs for the first 3 months of fiscal year
14 2014. If the Food and Drug Administration has car-
15 ryover balances for the process for the review of ab-
16 breviated applications for generic new animal drugs
17 in excess of 3 months of such operating reserves,
18 then this adjustment shall not be made. If this ad-
19 justment is necessary, then the rationale for the
20 amount of the increase shall be contained in the an-
21 nual notice setting fees for fiscal year 2013.

22 “(3) ANNUAL FEE SETTING.—The Secretary
23 shall establish, 60 days before the start of each fis-
24 cal year beginning after September 30, 2008, for
25 that fiscal year, abbreviated application fees, generic

1 new animal drug sponsor fees, and generic new ani-
2 mal drug product fees based on the revenue amounts
3 established under subsection (b) and the adjust-
4 ments provided under this subsection.

5 “(4) LIMIT.—The total amount of fees charged,
6 as adjusted under this subsection, for a fiscal year
7 may not exceed the total costs for such fiscal year
8 for the resources allocated for the process for the re-
9 view of abbreviated applications for generic new ani-
10 mal drugs.

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

16 “(e) EFFECT OF FAILURE TO PAY FEES.—An abbre-
17 viated application for a generic new animal drug sub-
18 mitted by a person subject to fees under subsection (a)
19 shall be considered incomplete and shall not be accepted
20 for filing by the Secretary until all fees owed by such per-
21 son have been paid. An investigational submission for a
22 generic new animal drug that is submitted by a person
23 subject to fees under subsection (a) shall be considered
24 incomplete and shall not be accepted for review by the Sec-
25 retary until all fees owed by such person have been paid.

1 The Secretary may discontinue review of any abbreviated
2 application for a generic new animal drug, supplemental
3 abbreviated application for a generic new animal drug, or
4 investigational submission for a generic new animal drug
5 from a person if such person has not submitted for pay-
6 ment all fees owed under this section by 30 days after
7 the date upon which they are due.

8 “(f) ASSESSMENT OF FEES.—

9 “(1) LIMITATION.—Fees may not be assessed
10 under subsection (a) for a fiscal year beginning after
11 fiscal year 2008 unless appropriations for salaries
12 and expenses of the Food and Drug Administration
13 for such fiscal year (excluding the amount of fees
14 appropriated for such fiscal year) are equal to or
15 greater than the amount of appropriations for the
16 salaries and expenses of the Food and Drug Admin-
17 istration for the fiscal year 2003 (excluding the
18 amount of fees appropriated for such fiscal year)
19 multiplied by the adjustment factor, with the base or
20 comparator being October 2002, applicable to the
21 fiscal year involved.

22 “(2) AUTHORITY.—If the Secretary does not
23 assess fees under subsection (a) during any portion
24 of a fiscal year because of paragraph (1) and if at
25 a later date in such fiscal year the Secretary may as-

1 sess such fees, the Secretary may assess and collect
2 such fees, without any modification in the rate, for
3 abbreviated applications, generic new animal drug
4 sponsors, and generic new animal drug products at
5 any time in such fiscal year notwithstanding the pro-
6 visions of subsection (a) relating to the date fees are
7 to be paid.

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

9 “(1) IN GENERAL.—Fees authorized under sub-
10 section (a) shall be collected and available for obliga-
11 tion only to the extent and in the amount provided
12 in advance in appropriations Acts. Such fees are au-
13 thorized to be appropriated to remain available until
14 expended. Such sums as may be necessary may be
15 transferred from the Food and Drug Administration
16 salaries and expenses appropriation account without
17 fiscal year limitation to such appropriation account
18 for salary and expenses with such fiscal year limita-
19 tion. The sums transferred shall be available solely
20 for the process for the review of abbreviated applica-
21 tions for generic new animal drugs.

22 “(2) COLLECTIONS AND APPROPRIATION
23 ACTS.—

24 “(A) IN GENERAL.—The fees authorized
25 by this section—

1 “(i) shall be retained in each fiscal
2 year in an amount not to exceed the
3 amount specified in appropriation Acts, or
4 otherwise made available for obligation for
5 such fiscal year; and

6 “(ii) shall only be collected and avail-
7 able to defray increases in the costs of the
8 resources allocated for the process for the
9 review of abbreviated applications for ge-
10 neric new animal drugs (including in-
11 creases in such costs for an additional
12 number of full-time equivalent positions in
13 the Department of Health and Human
14 Services to be engaged in such process)
15 over such costs, excluding costs paid from
16 fees collected under this section, for fiscal
17 year 2008 multiplied by the adjustment
18 factor, with the base or comparator being
19 October 2007.

20 “(B) COMPLIANCE.—The Secretary shall
21 be considered to have met the requirements of
22 subparagraph (A)(ii) in any fiscal year if the
23 costs funded by appropriations and allocated for
24 the process for the review of abbreviated appli-
25 cations for generic new animal drugs—

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

4 “(ii)(I) are more than 3 percent below
5 the level specified in subparagraph (A)(ii),
6 and fees assessed for the fiscal year fol-
7 lowing the subsequent fiscal year are de-
8 creased by the amount in excess of 3 per-
9 cent by which such costs fell below the
10 level specified in subparagraph (A)(ii); and

11 “(II) such costs are not more than 5
12 percent below the level specified in sub-
13 paragraph (A)(ii).

14 “(3) AUTHORIZATION OF APPROPRIATIONS.—
15 There are authorized to be appropriated for fees
16 under this section—

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

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

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

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

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

22 as adjusted to reflect adjustments in the total fee
23 revenues made under this section and changes in the
24 total amounts collected by abbreviated application

1 fees, generic new animal drug sponsor fees, and ge-
2 neric new animal drug product fees.

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

16 “(h) COLLECTION OF UNPAID FEES.—In any case
17 where the Secretary does not receive payment of a fee as-
18 sessed under subsection (a) within 30 days after it is due,
19 such fee shall be treated as a claim of the United States
20 Government subject to subchapter II of chapter 37 of title
21 31, United States Code.

22 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
23 TIONS, AND REFUNDS.—To qualify for consideration for
24 a waiver or reduction under subsection (d), or for a refund
25 of any fee collected in accordance with subsection (a), a

1 person shall submit to the Secretary a written request for
2 such waiver, reduction, or refund not later than 180 days
3 after such fee is due.

4 “(j) CONSTRUCTION.—This section may not be con-
5 strued to require that the number of full-time equivalent
6 positions in the Department of Health and Human Serv-
7 ices, for officers, employees, and advisory committees not
8 engaged in the process of the review of abbreviated appli-
9 cations for generic new animal drugs, be reduced to offset
10 the number of officers, employees, and advisory commit-
11 tees so engaged.

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

13 “(1) ABBREVIATED APPLICATION FOR A GE-
14 NERIC NEW ANIMAL DRUG.—The terms ‘abbreviated
15 application for a generic new animal drug’ and ‘ab-
16 breviated application’ mean an abbreviated applica-
17 tion for the approval of any generic new animal drug
18 submitted under section 512(b)(2). Such term does
19 not include a supplemental abbreviated application
20 for a generic new animal drug.

21 “(2) ADJUSTMENT FACTOR.—Subject to sub-
22 sections (f)(1) and (g)(2)(A)(ii), the term ‘adjust-
23 ment factor’ applicable to a fiscal year refers to the
24 formula set forth in section 735(8).

1 “(3) COSTS OF RESOURCES ALLOCATED FOR
2 THE PROCESS FOR THE REVIEW OF ABBREVIATED
3 APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—

4 The term ‘costs of resources allocated for the proc-
5 ess for the review of abbreviated applications for ge-
6 neric new animal drugs’ means the expenses in-
7 curred in connection with the process for the review
8 of abbreviated applications for generic new animal
9 drugs for—

10 “(A) officers and employees of the Food
11 and Drug Administration, contractors of the
12 Food and Drug Administration, advisory com-
13 mittees consulted with respect to the review of
14 specific abbreviated applications, supplemental
15 abbreviated applications, or investigational sub-
16 missions, and costs related to such officers, em-
17 ployees, committees, and contractors, including
18 costs for travel, education, and recruitment and
19 other personnel activities;

20 “(B) management of information, and the
21 acquisition, maintenance, and repair of com-
22 puter resources;

23 “(C) leasing, maintenance, renovation, and
24 repair of facilities and acquisition, maintenance,
25 and repair of fixtures, furniture, scientific

1 equipment, and other necessary materials and
2 supplies; and

3 “(D) collecting fees under this section and
4 accounting for resources allocated for the re-
5 view of abbreviated applications, supplemental
6 abbreviated applications, and investigational
7 submissions.

8 “(4) FINAL DOSAGE FORM.—The term ‘final
9 dosage form’ means, with respect to a generic new
10 animal drug product, a finished dosage form which
11 is approved for administration to an animal without
12 substantial further manufacturing. Such term in-
13 cludes generic new animal drug products intended
14 for mixing in animal feeds.

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

18 “(6) GENERIC NEW ANIMAL DRUG PRODUCT.—
19 The term ‘generic new animal drug product’ means
20 each specific strength or potency of a particular ac-
21 tive ingredient or ingredients in final dosage form
22 marketed by a particular manufacturer or dis-
23 tributor, which is uniquely identified by the labeler
24 code and product code portions of the national drug
25 code, and for which an abbreviated application for a

1 generic new animal drug or a supplemental abbrevi-
2 viated application has been approved.

3 “(7) GENERIC NEW ANIMAL DRUG SPONSOR.—
4 The term ‘generic new animal drug sponsor’ means
5 either an applicant named in an abbreviated applica-
6 tion for a generic new animal drug that has not been
7 withdrawn, or a person who has submitted an inves-
8 tigational submission for a generic new animal drug
9 that has not been terminated or otherwise rendered
10 inactive by the Secretary.

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

15 “(A) the filing of a claim for an investiga-
16 tional exemption under section 512(j) for a ge-
17 neric new animal drug intended to be the sub-
18 ject of an abbreviated application or a supple-
19 mental abbreviated application; or

20 “(B) the submission of information for the
21 purpose of enabling the Secretary to evaluate
22 the safety or effectiveness of a generic new ani-
23 mal drug in the event of the filing of an abbrevi-
24 viated application or supplemental abbreviated
25 application for such drug.

1 “(9) PERSON.—The term ‘person’ includes an
2 affiliate thereof (as such term is defined in section
3 735(11)).

4 “(10) PROCESS FOR THE REVIEW OF ABBRE-
5 VIATED APPLICATIONS FOR GENERIC NEW ANIMAL
6 DRUGS.—The term ‘process for the review of abbre-
7 viated applications for generic new animal drugs’
8 means the following activities of the Secretary with
9 respect to the review of abbreviated applications,
10 supplemental abbreviated applications, and inves-
11 tigational submissions:

12 “(A) The activities necessary for the re-
13 view of abbreviated applications, supplemental
14 abbreviated applications, and investigational
15 submissions.

16 “(B) The issuance of action letters which
17 approve abbreviated applications or supple-
18 mental abbreviated applications or which set
19 forth in detail the specific deficiencies in abbre-
20 viated applications, supplemental abbreviated
21 applications, or investigational submissions and,
22 where appropriate, the actions necessary to
23 place such applications, supplemental applica-
24 tions, or submissions in condition for approval.

1 “(C) The inspection of generic new animal
2 drug establishments and other facilities under-
3 taken as part of the Secretary’s review of pend-
4 ing abbreviated applications, supplemental ab-
5 breviated applications, and investigational sub-
6 missions.

7 “(D) Monitoring of research conducted in
8 connection with the review of abbreviated appli-
9 cations, supplemental abbreviated applications,
10 and investigational submissions.

11 “(E) The development of regulations and
12 policy related to the review of abbreviated appli-
13 cations, supplemental abbreviated applications,
14 and investigational submissions.

15 “(F) Development of standards for prod-
16 ucts subject to review.

17 “(G) Meetings between the agency and the
18 generic new animal drug sponsor.

19 “(H) Review of advertising and labeling
20 prior to approval of an abbreviated application
21 or supplemental abbreviated application, but
22 not such activities after a generic new animal
23 drug has been approved.

24 “(11) SUPPLEMENTAL ABBREVIATED APPLICA-
25 TION FOR GENERIC NEW ANIMAL DRUG.—The terms

1 ‘supplemental abbreviated application for a generic
2 new animal drug’ and ‘supplemental abbreviated ap-
3 plication’ mean a request to the Secretary to ap-
4 prove a change in an approved abbreviated applica-
5 tion.”.

6 **SEC. 4. ACCOUNTABILITY AND REPORTS.**

7 Part 5 of subchapter C of chapter VII of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.),
9 as added by section 3, is amended by inserting after sec-
10 tion 741 the following:

11 **“SEC. 742. REAUTHORIZATION; REPORTING REQUIRE-**
12 **MENTS.**

13 “(a) PERFORMANCE REPORTS.—Beginning with fis-
14 cal year 2009, not later than 60 days after the end of
15 each fiscal year during which fees are collected under this
16 part, the Secretary shall prepare and submit to the Com-
17 mittee on Health, Education, Labor, and Pensions of the
18 Senate, and the Committee on Energy and Commerce of
19 the House of Representatives a report concerning the
20 progress of the Food and Drug Administration in achiev-
21 ing the goals identified in the letters described in section
22 2(3) of the Animal Generic Drug User Fee Act of 2008
23 toward expediting the generic new animal drug develop-
24 ment process and the review of abbreviated applications
25 for generic new animal drugs, supplemental abbreviated

1 applications for generic new animal drugs, and investiga-
2 tional submissions for generic new animal drugs during
3 such fiscal year.

4 “(b) FISCAL REPORT.—Beginning with fiscal year
5 2009, not later than 120 days after the end of each fiscal
6 year during which fees are collected under this part, the
7 Secretary shall prepare and submit to Committee on
8 Health, Education, Labor, and Pensions of the Senate and
9 the Committee on Energy and Commerce of the House
10 of Representatives a report on the implementation of the
11 authority for such fees during such fiscal year and the
12 use, by the Food and Drug Administration, of the fees
13 collected during such fiscal year for which the report is
14 made.

15 “(c) PUBLIC AVAILABILITY.—The Secretary shall
16 make the reports required under subsections (a) and (b)
17 available to the public on the Internet Web site of the
18 Food and Drug Administration.

19 “(d) REAUTHORIZATION.—

20 “(1) CONSULTATION.—In developing rec-
21 ommendations to present to Congress with respect to
22 the goals, and plans for meeting the goals, for the
23 process for the review of abbreviated applications for
24 generic new animal drugs for the first 5 fiscal years
25 after fiscal year 2013, and for the reauthorization of

1 this part for such fiscal years, the Secretary shall
2 consult with—

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

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

7 “(C) scientific and academic experts;

8 “(D) veterinary professionals;

9 “(E) representatives of patient and con-
10 sumer advocacy groups; and

11 “(F) the regulated industry.

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

15 “(A) publish a notice in the Federal Reg-
16 ister requesting public input on the reauthoriza-
17 tion;

18 “(B) hold a public meeting at which the
19 public may present its views on the reauthoriza-
20 tion, including specific suggestions for changes
21 to the goals referred to in subsection (a);

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

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

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

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

14 “(A) present the recommendations devel-
15 oped under paragraph (1) to the congressional
16 committees specified in such paragraph;

17 “(B) publish such recommendations in the
18 Federal Register;

19 “(C) provide for a period of 30 days for
20 the public to provide written comments on such
21 recommendations;

22 “(D) hold a meeting at which the public
23 may present its views on such recommenda-
24 tions; and

1 “(E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
5 Not later than January 15, 2013, the Secretary
6 shall transmit to Congress the revised recommenda-
7 tions under paragraph (4), a summary of the views
8 and comments received under such paragraph, and
9 any changes made to the recommendations in re-
10 sponse to such views and comments.

11 “(6) MINUTES OF NEGOTIATION MEETINGS.—

12 “(A) PUBLIC AVAILABILITY.—Before pre-
13 senting the recommendations developed under
14 paragraphs (1) through (5) to Congress, the
15 Secretary shall make publicly available, on the
16 Internet Web site of the Food and Drug Ad-
17 ministration, minutes of all negotiation meet-
18 ings conducted under this subsection between
19 the Food and Drug Administration and the reg-
20 ulated industry.

21 “(B) CONTENT.—The minutes described
22 under subparagraph (A) shall summarize any
23 substantive proposal made by any party to the
24 negotiations as well as significant controversies

1 or differences of opinion during the negotiations
2 and their resolution.”.

3 **SEC. 5. SUNSET DATES.**

4 (a) **AUTHORIZATION.**—The amendments made by
5 section 3 shall cease to be effective October 1, 2013.

6 (b) **REPORTING REQUIREMENTS.**—The amendment
7 made by section 4 shall cease to be effective January 31,
8 2014.