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H. R. 1407

[Report No. 113–188]

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs.

IN THE HOUSE OF REPRESENTATIVES

APRIL 9, 2013

Mr. SHIMKUS (for himself, Mr. GARDNER, Mr. UPTON, Mr. PITTS, Mr. WAXMAN, Mr. PALLONE, Mr. BURGESS, Mr. GUTHRIE, and Mr. KINZINGER of Illinois) introduced the following bill; which was referred to the Committee on Energy and Commerce

AUGUST 2, 2013

Reported with amendments, 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 *italie*]

[For text of introduced bill, see copy of bill as introduced on April 9, 2013]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to
reauthorize user fee programs relating to 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,*
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Sec. 1. Table of Contents.

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

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

7 (a) *SHORT TITLE.*—This title may be cited as the
 8 *“Animal Drug User Fee Amendments of 2013”.*

9 (b) *FINDING.*—Congress finds that the fees authorized
 10 by the amendments made in this title 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

1 *and Human Services to the Chairman of the Committee on*
 2 *Energy and Commerce of the House of Representatives and*
 3 *the Chairman of the Committee on Health, Education,*
 4 *Labor, and Pensions of the Senate as set forth in the Con-*
 5 *gressional Record.*

6 **SEC. 102. DEFINITIONS.**

7 *Section 739 of the Federal Food, Drug, and Cosmetic*
 8 *Act (21 U.S.C. 379j–11) is amended to read as follows:*

9 **“SEC. 739. DEFINITIONS.**

10 *“For purposes of this part:*

11 *“(1) The term ‘animal drug application’ means*
 12 *an application for approval of any new animal drug*
 13 *submitted under section 512(b)(1). Such term does not*
 14 *include either a new animal drug application sub-*
 15 *mitted under section 512(b)(2) or a supplemental ani-*
 16 *mal drug application.*

17 *“(2) The term ‘supplemental animal drug appli-*
 18 *cation’ means—*

19 *“(A) a request to the Secretary to approve*
 20 *a change in an animal drug application which*
 21 *has been approved; or*

22 *“(B) a request to the Secretary to approve*
 23 *a change to an application approved under sec-*
 24 *tion 512(c)(2) for which data with respect to*
 25 *safety or effectiveness are required.*

1 “(3) The term ‘animal drug product’ means each
2 specific strength or potency of a particular active in-
3 gredient or ingredients in final dosage form marketed
4 by a particular manufacturer or distributor, which is
5 uniquely identified by the labeler code and product
6 code portions of the national drug code, and for which
7 an animal drug application or a supplemental ani-
8 mal drug application has been approved.

9 “(4) The term ‘animal drug establishment’
10 means a foreign or domestic place of business which
11 is at one general physical location consisting of one
12 or more buildings all of which are within 5 miles of
13 each other, at which one or more animal drug prod-
14 ucts are manufactured in final dosage form.

15 “(5) The term ‘investigational animal drug sub-
16 mission’ means—

17 “(A) the filing of a claim for an investiga-
18 tional exemption under section 512(j) for a new
19 animal drug intended to be the subject of an ani-
20 mal drug application or a supplemental animal
21 drug application; or

22 “(B) the submission of information for the
23 purpose of enabling the Secretary to evaluate the
24 safety or effectiveness of an animal drug applica-

1 *tion or supplemental animal drug application in*
2 *the event of their filing.*

3 “(6) *The term ‘animal drug sponsor’ means ei-*
4 *ther an applicant named in an animal drug applica-*
5 *tion that has not been withdrawn by the applicant*
6 *and for which approval has not been withdrawn by*
7 *the Secretary, or a person who has submitted an in-*
8 *vestigational animal drug submission that has not*
9 *been terminated or otherwise rendered inactive by the*
10 *Secretary.*

11 “(7) *The term ‘final dosage form’ means, with*
12 *respect to an animal drug product, a finished dosage*
13 *form which is approved for administration to an ani-*
14 *mal without substantial further manufacturing. Such*
15 *term includes animal drug products intended for mix-*
16 *ing in animal feeds.*

17 “(8) *The term ‘process for the review of animal*
18 *drug applications’ means the following activities of*
19 *the Secretary with respect to the review of animal*
20 *drug applications, supplemental animal drug appli-*
21 *cations, and investigational animal drug submissions:*

22 “(A) *The activities necessary for the review*
23 *of animal drug applications, supplemental ani-*
24 *mal drug applications, and investigational ani-*
25 *mal drug submissions.*

1 “(B) The issuance of action letters which
2 approve animal drug applications or supple-
3 mental animal drug applications or which set
4 forth in detail the specific deficiencies in animal
5 drug applications, supplemental animal drug
6 applications, or investigational animal drug
7 submissions and, where appropriate, the actions
8 necessary to place such applications, supple-
9 ments, or submissions in condition for approval.

10 “(C) The inspection of animal drug estab-
11 lishments and other facilities undertaken as part
12 of the Secretary’s review of pending animal drug
13 applications, supplemental animal drug applica-
14 tions, and investigational animal drug submis-
15 sions.

16 “(D) Monitoring of research conducted in
17 connection with the review of animal drug appli-
18 cations, supplemental animal drug applications,
19 and investigational animal drug submissions.

20 “(E) The development of regulations and
21 policy related to the review of animal drug ap-
22 plications, supplemental animal drug applica-
23 tions, and investigational animal drug submis-
24 sions.

1 “(F) *Development of standards for products*
2 *subject to review.*

3 “(G) *Meetings between the agency and the*
4 *animal drug sponsor.*

5 “(H) *Review of advertising and labeling*
6 *prior to approval of an animal drug application*
7 *or supplemental animal drug application, but*
8 *not after such application has been approved.*

9 “(9) *The term ‘costs of resources allocated for the*
10 *process for the review of animal drug applications’*
11 *means the expenses in connection with the process for*
12 *the review of animal drug applications for—*

13 “(A) *officers and employees of the Food and*
14 *Drug Administration, contractors of the Food*
15 *and Drug Administration, advisory committees*
16 *consulted with respect to the review of specific*
17 *animal drug applications, supplemental animal*
18 *drug applications, or investigational animal*
19 *drug submissions, and costs related to such offi-*
20 *cers, employees, committees, and contractors, in-*
21 *cluding costs for travel, education, and recruit-*
22 *ment and other personnel activities;*

23 “(B) *management of information and the*
24 *acquisition, maintenance, and repair of com-*
25 *puter resources;*

1 “(C) leasing, maintenance, renovation, and
2 repair of facilities and acquisition, maintenance,
3 and repair of fixtures, furniture, scientific equip-
4 ment, and other necessary materials and sup-
5 plies; and

6 “(D) collecting fees under section 740 and
7 accounting for resources allocated for the review
8 of animal drug applications, supplemental ani-
9 mal drug applications, and investigational ani-
10 mal drug submissions.

11 “(10) The term ‘adjustment factor’ applicable to
12 a fiscal year refers to the formula set forth in section
13 735(8) with the base or comparator month being Oc-
14 tober 2002.

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

17 “(12) The term ‘affiliate’ refers to the definition
18 set forth in section 735(11).”.

19 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
20 **FEES.**

21 Section 740 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 379j–12) is amended to read as follows:

1 **“SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
2 **FEES.**

3 “(a) *TYPES OF FEES.*—Beginning in fiscal year 2004,
4 *the Secretary shall assess and collect fees in accordance with*
5 *this section as follows:*

6 “(1) *ANIMAL DRUG APPLICATION AND SUPPLE-*
7 *MENT FEE.*—

8 “(A) *IN GENERAL.*—Each person that sub-
9 *mits, on or after September 1, 2003, an animal*
10 *drug application or a supplemental animal drug*
11 *application shall be subject to a fee as follows:*

12 “(i) *A fee established in subsection (c)*
13 *for an animal drug application, except an*
14 *animal drug application described in sec-*
15 *tion 512(d)(4).*

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

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

22 “(II) *an animal drug application*
23 *described in section 512(d)(4).*

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

1 *the animal drug application or supplemental*
2 *animal drug application.*

3 “(C) *EXCEPTION FOR PREVIOUSLY FILED*
4 *APPLICATION OR SUPPLEMENT.—If an animal*
5 *drug application or a supplemental animal drug*
6 *application was submitted by a person that paid*
7 *the fee for such application or supplement, was*
8 *accepted for filing, and was not approved or was*
9 *withdrawn (without a waiver or refund), the*
10 *submission of an animal drug application or a*
11 *supplemental animal drug application for the*
12 *same product by the same person (or the person’s*
13 *licensee, assignee, or successor) shall not be sub-*
14 *ject to a fee under subparagraph (A).*

15 “(D) *REFUND OF FEE IF APPLICATION RE-*
16 *FUSED FOR FILING.—The Secretary shall refund*
17 *75 percent of the fee paid under subparagraph*
18 *(B) for any animal drug application or supple-*
19 *mental animal drug application which is refused*
20 *for filing.*

21 “(E) *REFUND OF FEE IF APPLICATION*
22 *WITHDRAWN.—If an animal drug application or*
23 *a supplemental animal drug application is with-*
24 *drawn after the application or supplement was*
25 *filed, the Secretary may refund the fee or portion*

1 *of the fee paid under subparagraph (B) if no*
2 *substantial work was performed on the applica-*
3 *tion or supplement after the application or sup-*
4 *plement was filed. The Secretary shall have the*
5 *sole discretion to refund the fee under this para-*
6 *graph. A determination by the Secretary con-*
7 *cerning a refund under this paragraph shall not*
8 *be reviewable.*

9 “(2) *ANIMAL DRUG PRODUCT FEE.*—

10 “(A) *IN GENERAL.*—*Each person—*

11 “(i) *who is named as the applicant in*
12 *an animal drug application or supple-*
13 *mental animal drug application for an ani-*
14 *mal drug product which has been submitted*
15 *for listing under section 510; and*

16 “(ii) *who, after September 1, 2003, had*
17 *pending before the Secretary an animal*
18 *drug application or supplemental animal*
19 *drug application,*

20 *shall pay for each such animal drug product the*
21 *annual fee established in subsection (c).*

22 “(B) *PAYMENT; FEE DUE DATE.*—*Such fee*
23 *shall be payable for the fiscal year in which the*
24 *animal drug product is first submitted for list-*
25 *ing under section 510, or is submitted for re-*

1 *listing under section 510 if the animal drug*
2 *product has been withdrawn from listing and re-*
3 *listed. After such fee is paid for that fiscal year,*
4 *such fee shall be due each subsequent fiscal year*
5 *that the product remains listed, upon the later*
6 *of—*

7 “(i) *the first business day after the*
8 *date of enactment of an appropriations Act*
9 *providing for the collection and obligation*
10 *of fees for such fiscal year under this sec-*
11 *tion; or*

12 “(ii) *January 31 of each year.*

13 “(C) *LIMITATION.—Such fee shall be paid*
14 *only once for each animal drug product for a fis-*
15 *cal year in which the fee is payable.*

16 “(3) *ANIMAL DRUG ESTABLISHMENT FEE.—*

17 “(A) *IN GENERAL.—Each person—*

18 “(i) *who owns or operates, directly or*
19 *through an affiliate, an animal drug estab-*
20 *lishment;*

21 “(ii) *who is named as the applicant in*
22 *an animal drug application or supple-*
23 *mental animal drug application for an ani-*
24 *mal drug product which has been submitted*
25 *for listing under section 510; and*

1 “(iii) who, after September 1, 2003,
2 had pending before the Secretary an animal
3 drug application or supplemental animal
4 drug application,
5 shall be assessed an annual establishment fee as
6 established in subsection (c) for each animal
7 drug establishment listed in its approved animal
8 drug application as an establishment that manu-
9 factures the animal drug product named in the
10 application.

11 “(B) PAYMENT; FEE DUE DATE.—The an-
12 nual establishment fee shall be assessed in each
13 fiscal year in which the animal drug product
14 named in the application is assessed a fee under
15 paragraph (2) unless the animal drug establish-
16 ment listed in the application does not engage in
17 the manufacture of the animal drug product dur-
18 ing the fiscal year. The fee under this paragraph
19 for a fiscal year shall be due upon the later of—

20 “(i) the first business day after the
21 date of enactment of an appropriations Act
22 providing for the collection and obligation
23 of fees for such fiscal year under this sec-
24 tion; or

25 “(ii) January 31 of each year.

1 “(C) *LIMITATION.*—

2 “(i) *IN GENERAL.*—*An establishment*
3 *shall be assessed only one fee per fiscal year*
4 *under this section, subject to clause (ii).*

5 “(ii) *CERTAIN MANUFACTURERS.*—*If a*
6 *single establishment manufactures both ani-*
7 *mal drug products and prescription drug*
8 *products, as defined in section 735(3), such*
9 *establishment shall be assessed both the ani-*
10 *mal drug establishment fee and the pre-*
11 *scription drug establishment fee, as set forth*
12 *in section 736(a)(2), within a single fiscal*
13 *year.*

14 “(4) *ANIMAL DRUG SPONSOR FEE.*—

15 “(A) *IN GENERAL.*—*Each person—*

16 “(i) *who meets the definition of an*
17 *animal drug sponsor within a fiscal year;*
18 *and*

19 “(ii) *who, after September 1, 2003, had*
20 *pending before the Secretary an animal*
21 *drug application, a supplemental animal*
22 *drug application, or an investigational ani-*
23 *mal drug submission,*

24 *shall be assessed an annual sponsor fee as estab-*
25 *lished under subsection (c).*

1 “(B) *PAYMENT; FEE DUE DATE.*—*The fee*
 2 *under this paragraph for a fiscal year shall be*
 3 *due upon the later of—*

4 “(i) *the first business day after the*
 5 *date of enactment of an appropriations Act*
 6 *providing for the collection and obligation*
 7 *of fees for such fiscal year under this sec-*
 8 *tion; or*

9 “(ii) *January 31 of each year.*

10 “(C) *LIMITATION.*—*Each animal drug*
 11 *sponsor shall pay only one such fee each fiscal*
 12 *year.*

13 “(b) *FEE REVENUE AMOUNTS.*—

14 “(1) *IN GENERAL.*—*Subject to subsections (c),*
 15 *(d), (f), and (g)—*

16 “(A) *for fiscal year 2014, the fees required*
 17 *under subsection (a) shall be established to gen-*
 18 *erate a total revenue amount of \$23,600,000; and*

19 “(B) *for each of fiscal years 2015 through*
 20 *2018, the fees required under subsection (a) shall*
 21 *be established to generate a total revenue amount*
 22 *of \$21,600,000.*

23 “(2) *TYPES OF FEES.*—*Of the total revenue*
 24 *amount determined for a fiscal year under paragraph*
 25 *(1)—*

1 “(A) 20 percent shall be derived from fees
2 under subsection (a)(1) (relating to animal drug
3 applications and supplements);

4 “(B) 27 percent shall be derived from fees
5 under subsection (a)(2) (relating to animal drug
6 products);

7 “(C) 26 percent shall be derived from fees
8 under subsection (a)(3) (relating to animal drug
9 establishments); and

10 “(D) 27 percent shall be derived from fees
11 under subsection (a)(4) (relating to animal drug
12 sponsors).

13 “(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

14 “(1) ANNUAL FEE SETTING.—The Secretary shall
15 establish, 60 days before the start of each fiscal year
16 beginning after September 30, 2003, for that fiscal
17 year, animal drug application fees, supplemental ani-
18 mal drug application fees, animal drug sponsor fees,
19 animal drug establishment fees, and animal drug
20 product fees based on the revenue amounts established
21 under subsection (b) and the adjustments provided
22 under this subsection.

23 “(2) INFLATION ADJUSTMENT.—For fiscal year
24 2015 and subsequent fiscal years, the revenue
25 amounts established in subsection (b) shall be adjusted

1 *by the Secretary by notice, published in the Federal*
2 *Register, for a fiscal year, by an amount equal to the*
3 *sum of—*

4 “(A) one;

5 “(B) *the average annual percent change in*
6 *the cost, per full-time equivalent position of the*
7 *Food and Drug Administration, of all personnel*
8 *compensation and benefits paid with respect to*
9 *such positions for the first 3 of the preceding 4*
10 *fiscal years for which data are available, multi-*
11 *plied by the average proportion of personnel*
12 *compensation and benefits costs to total Food*
13 *and Drug Administration costs for the first 3*
14 *years of the preceding 4 fiscal years for which*
15 *data are available; and*

16 “(C) *the average annual percent change*
17 *that occurred in the Consumer Price Index for*
18 *urban consumers (Washington-Baltimore, DC-*
19 *MD-VA-WV; not seasonally adjusted; all items*
20 *less food and energy; annual index) for the first*
21 *3 years of the preceding 4 years for which data*
22 *are available multiplied by the average propor-*
23 *tion of all costs other than personnel compensa-*
24 *tion and benefits costs to total Food and Drug*
25 *Administration costs for the first 3 years of the*

1 *preceding 4 fiscal years for which data are avail-*
2 *able.*

3 *The adjustment made each fiscal year under this*
4 *paragraph shall be added on a compounded basis to*
5 *the sum of all adjustments made each fiscal year after*
6 *fiscal year 2014 under this paragraph.*

7 “(3) *WORKLOAD ADJUSTMENT.—For fiscal year*
8 *2015 and subsequent fiscal years, after the revenue*
9 *amounts established in subsection (b) are adjusted for*
10 *inflation in accordance with paragraph (2), the rev-*
11 *enue amounts shall be further adjusted for such fiscal*
12 *year to reflect changes in the workload of the Sec-*
13 *retary for the process for the review of animal drug*
14 *applications. With respect to such adjustment—*

15 “(A) *such adjustment shall be determined*
16 *by the Secretary based on a weighted average of*
17 *the change in the total number of animal drug*
18 *applications, supplemental animal drug applica-*
19 *tions for which data with respect to safety or ef-*
20 *fectiveness are required, manufacturing supple-*
21 *mental animal drug applications, investiga-*
22 *tional animal drug study submissions, and in-*
23 *vestigational animal drug protocol submissions*
24 *submitted to the Secretary;*

1 “(B) the Secretary shall publish in the Fed-
2 eral Register the fees resulting from such adjust-
3 ment and the supporting methodologies; and

4 “(C) under no circumstances shall such ad-
5 justment result in fee revenues for a fiscal year
6 that are less than the fee revenues for that fiscal
7 year established in subsection (b), as adjusted for
8 inflation under paragraph (2).

9 “(4) FINAL YEAR ADJUSTMENT.—For fiscal year
10 2018, the Secretary may, in addition to other adjust-
11 ments under this subsection, further increase the fees
12 under this section, if such an adjustment is necessary
13 to provide for up to 3 months of operating reserves of
14 carryover user fees for the process for the review of
15 animal drug applications for the first 3 months of fis-
16 cal year 2019. If the Food and Drug Administration
17 has carryover balances for the process for the review
18 of animal drug applications in excess of 3 months of
19 such operating reserves, then this adjustment will not
20 be made. If this adjustment is necessary, then the ra-
21 tionale for the amount of the increase shall be con-
22 tained in the annual notice setting fees for fiscal year
23 2018.

24 “(5) LIMIT.—The total amount of fees charged,
25 as adjusted under this subsection, for a fiscal year

1 *may not exceed the total costs for such fiscal year for*
2 *the resources allocated for the process for the review*
3 *of animal drug applications.*

4 “(d) *FEE WAIVER OR REDUCTION.*—

5 “(1) *IN GENERAL.*—*The Secretary shall grant a*
6 *waiver from or a reduction of one or more fees as-*
7 *essed under subsection (a) where the Secretary finds*
8 *that—*

9 “(A) *the assessment of the fee would present*
10 *a significant barrier to innovation because of*
11 *limited resources available to such person or*
12 *other circumstances;*

13 “(B) *the fees to be paid by such person will*
14 *exceed the anticipated present and future costs*
15 *incurred by the Secretary in conducting the*
16 *process for the review of animal drug applica-*
17 *tions for such person;*

18 “(C) *the animal drug application or supple-*
19 *mental animal drug application is intended sole-*
20 *ly to provide for use of the animal drug in—*

21 “(i) *a Type B medicated feed (as de-*
22 *finied in section 558.3(b)(3) of title 21, Code*
23 *of Federal Regulations (or any successor*
24 *regulation)) intended for use in the manu-*

1 *facture of Type C free-choice medicated*
 2 *feeds; or*

3 “(ii) *a Type C free-choice medicated*
 4 *feed (as defined in section 558.3(b)(4) of*
 5 *title 21, Code of Federal Regulations (or*
 6 *any successor regulation));*

7 “(D) *the animal drug application or sup-*
 8 *plemental animal drug application is intended*
 9 *solely to provide for a minor use or minor spe-*
 10 *cies indication; or*

11 “(E) *the sponsor involved is a small busi-*
 12 *ness submitting its first animal drug application*
 13 *to the Secretary for review.*

14 “(2) *USE OF STANDARD COSTS.—In making the*
 15 *finding in paragraph (1)(B), the Secretary may use*
 16 *standard costs.*

17 “(3) *RULES FOR SMALL BUSINESSES.—*

18 “(A) *DEFINITION.—In paragraph (1)(E),*
 19 *the term ‘small business’ means an entity that*
 20 *has fewer than 500 employees, including employ-*
 21 *ees of affiliates.*

22 “(B) *WAIVER OF APPLICATION FEE.—The*
 23 *Secretary shall waive under paragraph (1)(E)*
 24 *the application fee for the first animal drug ap-*
 25 *plication that a small business or its affiliate*

1 *submits to the Secretary for review. After a small*
2 *business or its affiliate is granted such a waiver,*
3 *the small business or its affiliate shall pay ap-*
4 *plication fees for all subsequent animal drug ap-*
5 *plications and supplemental animal drug appli-*
6 *cations for which safety or effectiveness data are*
7 *required in the same manner as an entity that*
8 *does not qualify as a small business.*

9 *“(C) CERTIFICATION.—The Secretary shall*
10 *require any person who applies for a waiver*
11 *under paragraph (1)(E) to certify their quali-*
12 *fication for the waiver. The Secretary shall peri-*
13 *odically publish in the Federal Register a list of*
14 *persons making such certifications.*

15 *“(e) EFFECT OF FAILURE TO PAY FEES.—An animal*
16 *drug application or supplemental animal drug application*
17 *submitted by a person subject to fees under subsection (a)*
18 *shall be considered incomplete and shall not be accepted for*
19 *filing by the Secretary until all fees owed by such person*
20 *have been paid. An investigational animal drug submission*
21 *under section 739(5)(B) that is submitted by a person sub-*
22 *ject to fees under subsection (a) shall be considered incom-*
23 *plete and shall not be accepted for review by the Secretary*
24 *until all fees owed by such person have been paid. The Sec-*
25 *retary may discontinue review of any animal drug applica-*

1 *tion, supplemental animal drug application, or investiga-*
 2 *tional animal drug submission from a person if such person*
 3 *has not submitted for payment all fees owed under this sec-*
 4 *tion by 30 days after the date upon which they are due.*

5 “(f) *ASSESSMENT OF FEES.*—

6 “(1) *LIMITATION.*—*Fees may not be assessed*
 7 *under subsection (a) for a fiscal year beginning after*
 8 *fiscal year 2003 unless appropriations for salaries*
 9 *and expenses of the Food and Drug Administration*
 10 *for such fiscal year (excluding the amount of fees ap-*
 11 *propriated for such fiscal year) are equal to or greater*
 12 *than the amount of appropriations for the salaries*
 13 *and expenses of the Food and Drug Administration*
 14 *for the fiscal year 2003 (excluding the amount of fees*
 15 *appropriated for such fiscal year) multiplied by the*
 16 *adjustment factor applicable to the fiscal year in-*
 17 *volved.*

18 “(2) *AUTHORITY.*—*If the Secretary does not as-*
 19 *sess fees under subsection (a) during any portion of*
 20 *a fiscal year because of paragraph (1) and if at a*
 21 *later date in such fiscal year the Secretary may assess*
 22 *such fees, the Secretary may assess and collect such*
 23 *fees, without any modification in the rate, for animal*
 24 *drug applications, supplemental animal drug appli-*
 25 *cations, investigational animal drug submissions,*

1 *animal drug sponsors, animal drug establishments,*
2 *and animal drug products at any time in such fiscal*
3 *year notwithstanding the provisions of subsection (a)*
4 *relating to the date fees are to be paid.*

5 “(g) *CREDITING AND AVAILABILITY OF FEES.*—

6 “(1) *IN GENERAL.*—Subject to paragraph (2)(C),
7 *fees authorized under subsection (a) shall be collected*
8 *and available for obligation only to the extent and in*
9 *the amount provided in advance in appropriations*
10 *Acts. Such fees are authorized to be appropriated to*
11 *remain available until expended. Such sums as may*
12 *be necessary may be transferred from the Food and*
13 *Drug Administration salaries and expenses appro-*
14 *priation account without fiscal year limitation to*
15 *such appropriation account for salary and expenses*
16 *with such fiscal year limitation. The sums transferred*
17 *shall be available solely for the process for the review*
18 *of animal drug applications.*

19 “(2) *COLLECTIONS AND APPROPRIATION ACTS.*—

20 “(A) *IN GENERAL.*—The fees authorized by
21 *this section—*

22 “(i) *subject to subparagraph (C), shall*
23 *be collected and available in each fiscal year*
24 *in an amount not to exceed the amount*
25 *specified in appropriation Acts, or other-*

1 *wise made available for obligation for such*
2 *fiscal year; and*

3 “(ii) *shall be available to defray in-*
4 *creases in the costs of the resources allocated*
5 *for the process for the review of animal drug*
6 *applications (including increases in such*
7 *costs for an additional number of full-time*
8 *equivalent positions in the Department of*
9 *Health and Human Services to be engaged*
10 *in such process) over such costs, excluding*
11 *costs paid from fees collected under this sec-*
12 *tion, for fiscal year 2003 multiplied by the*
13 *adjustment factor.*

14 “(B) COMPLIANCE.—*The Secretary shall be*
15 *considered to have met the requirements of sub-*
16 *paragraph (A)(ii) in any fiscal year if the costs*
17 *funded by appropriations and allocated for the*
18 *process for the review of animal drug applica-*
19 *tions—*

20 “(i) *are not more than 3 percent below*
21 *the level specified in subparagraph (A)(ii);*
22 *or*

23 “(ii)(I) *are more than 3 percent below*
24 *the level specified in subparagraph (A)(ii),*
25 *and fees assessed for the fiscal year fol-*

lowing the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

“(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

“(C) *PROVISION FOR EARLY PAYMENTS.*—
Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

“(3) *AUTHORIZATION OF APPROPRIATIONS.*—For each of the fiscal years 2014 through 2018, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4).

“(4) *OFFSET OF OVERCOLLECTIONS; RECOVERY OF COLLECTION SHORTFALLS.*—

“(A) *OFFSET OF OVERCOLLECTIONS.*—If the sum of the cumulative amount of fees collected under this section for fiscal years 2014 through

2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 (including any increased fee collections attributable to subparagraph (B)), exceeds the cumulative amount appropriated pursuant to paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.

“(B) *RECOVERY OF COLLECTION SHORT-FALLS.*—

“(i) *FISCAL YEAR 2016.*—For fiscal year 2016, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2014 falls below the amount of fees authorized for fiscal year 2014 under paragraph (3).

“(ii) *FISCAL YEAR 2017.*—For fiscal year 2017, the amount of fees otherwise au-

1 *thorized to be collected under this section*
2 *shall be increased by the amount, if any, by*
3 *which the amount collected under this sec-*
4 *tion and appropriated for fiscal year 2015*
5 *falls below the amount of fees authorized for*
6 *fiscal year 2015 under paragraph (3).*

7 *“(iii) FISCAL YEAR 2018.—For fiscal*
8 *year 2018, the amount of fees otherwise au-*
9 *thorized to be collected under this section*
10 *(including any reduction in the authorized*
11 *amount under subparagraph (A)), shall be*
12 *increased by the cumulative amount, if any,*
13 *by which the amount collected under this*
14 *section and appropriated for fiscal years*
15 *2016 and 2017 (including estimated collec-*
16 *tions for fiscal year 2017) falls below the*
17 *cumulative amount of fees authorized under*
18 *paragraph (3) for fiscal years 2016 and*
19 *2017.*

20 *“(h) COLLECTION OF UNPAID FEES.—In any case*
21 *where the Secretary does not receive payment of a fee as-*
22 *sessed under subsection (a) within 30 days after it is due,*
23 *such fee shall be treated as a claim of the United States*
24 *Government subject to subchapter II of chapter 37 of title*
25 *31, United States Code.*

1 “(i) *WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS,*
 2 *AND REFUNDS.*—*To qualify for consideration for a waiver*
 3 *or reduction under subsection (d), or for a refund of any*
 4 *fee collected in accordance with subsection (a), a person*
 5 *shall submit to the Secretary a written request for such*
 6 *waiver, reduction, or refund not later than 180 days after*
 7 *such fee is due.*

8 “(j) *CONSTRUCTION.*—*This section may not be con-*
 9 *strued to require that the number of full-time equivalent*
 10 *positions in the Department of Health and Human Serv-*
 11 *ices, for officers, employees, and advisory committees not*
 12 *engaged in the process of the review of animal drug applica-*
 13 *tions, be reduced to offset the number of officers, employees,*
 14 *and advisory committees so engaged.*

15 “(k) *ABBREVIATED NEW ANIMAL DRUG APPLICA-*
 16 *TIONS.*—*The Secretary shall—*

17 “(1) *to the extent practicable, segregate the re-*
 18 *view of abbreviated new animal drug applications*
 19 *from the process for the review of animal drug appli-*
 20 *cations; and*

21 “(2) *adopt other administrative procedures to*
 22 *ensure that review times of abbreviated new animal*
 23 *drug applications do not increase from their current*
 24 *level due to activities under the user fee program.”.*

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

2 *Section 740A of the Federal Food, Drug, and Cosmetic*
3 *Act (21 U.S.C. 379j–13) is amended to read as follows:*

4 **“SEC. 740A. REAUTHORIZATION; REPORTING REQUIRE-**
5 **MENTS.**

6 *“(a) PERFORMANCE REPORT.—Beginning with fiscal*
7 *year 2014, not later than 120 days after the end of each*
8 *fiscal year during which fees are collected under this part,*
9 *the Secretary shall prepare and submit to the Committee*
10 *on Energy and Commerce of the House of Representatives*
11 *and the Committee on Health, Education, Labor, and Pen-*
12 *sions of the Senate a report concerning the progress of the*
13 *Food and Drug Administration in achieving the goals iden-*
14 *tified in the letters described in section 101(b) of the Animal*
15 *Drug User Fee Amendments of 2013 toward expediting the*
16 *animal drug development process and the review of the new*
17 *and supplemental animal drug applications and investiga-*
18 *tional animal drug submissions during such fiscal year, the*
19 *future plans of the Food and Drug Administration for meet-*
20 *ing the goals, the review times for abbreviated new animal*
21 *drug applications, and the administrative procedures*
22 *adopted by the Food and Drug Administration to ensure*
23 *that review times for abbreviated new animal drug applica-*
24 *tions are not increased from their current level due to ac-*
25 *tivities under the user fee program.*

1 “(b) *FISCAL REPORT.*—Beginning with fiscal year
 2 2014, not later than 120 days after the end of each fiscal
 3 year during which fees are collected under this part, the
 4 Secretary shall prepare and submit to the Committee on
 5 Energy and Commerce of the House of Representatives and
 6 the Committee on Health, Education, Labor, and Pensions
 7 of the Senate a report on the implementation of the author-
 8 ity for such fees during such fiscal year and the use, by
 9 the Food and Drug Administration, of the fees collected dur-
 10 ing such fiscal year for which the report is made.

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

15 “(d) *REAUTHORIZATION.*—

16 “(1) *CONSULTATION.*—In developing rec-
 17 ommendations to present to the Congress with respect
 18 to the goals, and plans for meeting the goals, for the
 19 process for the review of animal drug applications for
 20 the first 5 fiscal years after fiscal year 2018, and for
 21 the reauthorization of this part for such fiscal years,
 22 the Secretary shall consult with—

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

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

3 “(C) scientific and academic experts;

4 “(D) veterinary professionals;

5 “(E) representatives of patient and con-
6 sumer advocacy groups; and

7 “(F) the regulated industry.

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

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

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

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

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

23 “(3) PERIODIC CONSULTATION.—Not less fre-
24 quently than once every 4 months during negotiations
25 with the regulated industry, the Secretary shall hold

1 *discussions with representatives of veterinary, patient,*
2 *and consumer advocacy groups to continue discus-*
3 *sions of their views on the reauthorization and their*
4 *suggestions for changes to this part as expressed*
5 *under paragraph (2).*

6 “(4) *PUBLIC REVIEW OF RECOMMENDATIONS.—*
7 *After negotiations with the regulated industry, the*
8 *Secretary shall—*

9 “(A) *present the recommendations developed*
10 *under paragraph (1) to the congressional com-*
11 *mittees specified in such paragraph;*

12 “(B) *publish such recommendations in the*
13 *Federal Register;*

14 “(C) *provide for a period of 30 days for the*
15 *public to provide written comments on such rec-*
16 *ommendations;*

17 “(D) *hold a meeting at which the public*
18 *may present its views on such recommendations;*
19 *and*

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

23 “(5) *TRANSMITTAL OF RECOMMENDATIONS.—Not*
24 *later than January 15, 2018, the Secretary shall*
25 *transmit to Congress the revised recommendations*

1 *under paragraph (4), a summary of the views and*
 2 *comments received under such paragraph, and any*
 3 *changes made to the recommendations in response to*
 4 *such views and comments.*

5 *“(6) MINUTES OF NEGOTIATION MEETINGS.—*

6 *“(A) PUBLIC AVAILABILITY.—Before pre-*
 7 *senting the recommendations developed under*
 8 *paragraphs (1) through (5) to Congress, the Sec-*
 9 *retary shall make publicly available, on the*
 10 *Internet Web site of the Food and Drug Admin-*
 11 *istration, minutes of Public Law 110-316 (122*
 12 *Stat. 3509)” all negotiation meetings conducted*
 13 *under this subsection between the Food and Drug*
 14 *Administration and the regulated industry.*

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

21 **SEC. 105. SAVINGS CLAUSE.**

22 *Notwithstanding the amendments made by this title,*
 23 *part 4 of subchapter C of chapter VII of the Federal Food,*
 24 *Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in*
 25 *effect on the day before the date of the enactment of this*

1 *title, shall continue to be in effect with respect to animal*
 2 *drug applications and supplemental animal drug applica-*
 3 *tions (as defined in such part as of such day) that on or*
 4 *after October 1, 2008, but before October 1, 2013, were ac-*
 5 *cepted by the Food and Drug Administration for filing with*
 6 *respect to assessing and collecting any fee required by such*
 7 *part for a fiscal year prior to fiscal year 2014.*

8 **SEC. 106. EFFECTIVE DATE.**

9 *The amendments made by this title shall take effect*
 10 *on October 1, 2013, or the date of enactment of this title,*
 11 *whichever is later, except that fees under part 4 of sub-*
 12 *chapter C of chapter VII of the Federal Food, Drug, and*
 13 *Cosmetic Act, as amended by this title, shall be assessed for*
 14 *all animal drug applications and supplemental animal*
 15 *drug applications received on or after October 1, 2013, re-*
 16 *gardless of the date of the enactment of this title.*

17 **SEC. 107. SUNSET DATES.**

18 *(a) AUTHORIZATION.—Section 740 of the Federal*
 19 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) shall*
 20 *cease to be effective October 1, 2018.*

21 *(b) REPORTING REQUIREMENTS.—Section 740A of the*
 22 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
 23 *13) shall cease to be effective January 31, 2019.*

24 *(c) PREVIOUS SUNSET PROVISION.—*

1 (1) *IN GENERAL.*—Section 108 of the Animal
 2 *Drug User Fee Amendments of 2008 (Public Law*
 3 *110–316) is repealed.*

4 (2) *CONFORMING AMENDMENT.*—Public Law
 5 110–316 (122 Stat. 3509) is amended in the table of
 6 contents in section 1, by striking the item relating to
 7 section 108.

8 (d) *TECHNICAL CLARIFICATION.*—Effective November
 9 18, 2003, section 5 of the Animal Drug User Fee Act of
 10 2003 (Public Law 108–130) is repealed.

11 ***TITLE II—ANIMAL GENERIC*** 12 ***DRUG USER FEE AMENDMENTS***

13 ***SECTION 201. SHORT TITLE; FINDING.***

14 (a) *SHORT TITLE.*—This title may be cited as the
 15 “Animal Generic Drug User Fee Amendments of 2013”.

16 (b) *FINDING.*—The fees authorized by this title will be
 17 dedicated toward expediting the generic new animal drug
 18 development process and the review of abbreviated applica-
 19 tions for generic new animal drugs, supplemental abbrevi-
 20 ated applications for generic new animal drugs, and in-
 21 vestigational submissions for generic new animal drugs as
 22 set forth in the goals identified in the letters from the Sec-
 23 retary of Health and Human Services to the Chairman of
 24 the Committee on Energy and Commerce of the House of
 25 Representatives and the Chairman of the Committee on

1 *Health, Education, Labor, and Pensions of the Senate as*
 2 *set forth in the Congressional Record.*

3 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**
 4 **ANIMAL DRUG FEES.**

5 *Section 741 of the Federal Food, Drug, and Cosmetic*
 6 *Act (21 U.S.C. 379j–21) is amended to read as follows:*

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

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

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

13 *“(A) IN GENERAL.—Each person that sub-*
 14 *mits, on or after July 1, 2008, an abbreviated*
 15 *application for a generic new animal drug shall*
 16 *be subject to a fee as established in subsection (c)*
 17 *for such an application.*

18 *“(B) PAYMENT.—The fee required by sub-*
 19 *paragraph (A) shall be due upon submission of*
 20 *the abbreviated application.*

21 *“(C) EXCEPTIONS.—*

22 *“(i) PREVIOUSLY FILED APPLICA-*
 23 *TION.—If an abbreviated application was*
 24 *submitted by a person that paid the fee for*
 25 *such application, was accepted for filing,*

1 *and was not approved or was withdrawn*
 2 *(without a waiver or refund), the submis-*
 3 *sion of an abbreviated application for the*
 4 *same product by the same person (or the*
 5 *person’s licensee, assignee, or successor)*
 6 *shall not be subject to a fee under subpara-*
 7 *graph (A).*

8 “(ii) *CERTAIN ABBREVIATED APPLICA-*
 9 *TIONS INVOLVING COMBINATION ANIMAL*
 10 *DRUGS.—An abbreviated application for an*
 11 *animal drug described in section 512(d)(4)*
 12 *and submitted on or after October 1, 2013,*
 13 *shall be subject to a fee equal to 50 percent*
 14 *of the amount of the abbreviated application*
 15 *fee established in subsection (c).*

16 “(D) *REFUND OF FEE IF APPLICATION RE-*
 17 *FUSED FOR FILING.—The Secretary shall refund*
 18 *75 percent of the fee paid under subparagraph*
 19 *(B) for any abbreviated application which is re-*
 20 *fused for filing.*

21 “(E) *REFUND OF FEE IF APPLICATION*
 22 *WITHDRAWN.—If an abbreviated application is*
 23 *withdrawn after the application was filed, the*
 24 *Secretary may refund the fee or portion of the fee*
 25 *paid under subparagraph (B) if no substantial*

work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

“(2) *GENERIC NEW ANIMAL DRUG PRODUCT FEE.*—

“(A) *IN GENERAL.*—Each person—

“(i) who is named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product which has been submitted for listing under section 510; and

“(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application or supplemental abbreviated application,

shall pay for each such generic new animal drug product the annual fee established in subsection (c).

“(B) *PAYMENT; FEE DUE DATE.*—Such fee shall be payable for the fiscal year in which the generic new animal drug product is first submitted for listing under section 510, or is sub-

mitted for relisting under section 510 if the generic new animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

“(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

“(ii) January 31 of each year.

“(C) *LIMITATION.*—Such fee shall be paid only once for each generic new animal drug product for a fiscal year in which the fee is payable.

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

“(A) *IN GENERAL.*—Each person—

“(i) who meets the definition of a generic new animal drug sponsor within a fiscal year; and

“(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated

1 *application, a supplemental abbreviated ap-*
2 *plication, or an investigational submission,*
3 *shall be assessed an annual generic new animal*
4 *drug sponsor fee as established under subsection*
5 *(c).*

6 “(B) *PAYMENT; FEE DUE DATE.*—*Such fee*
7 *shall be due each fiscal year upon the later of—*

8 “(i) *the first business day after the*
9 *date of enactment of an appropriations Act*
10 *providing for the collection and obligation*
11 *of fees for such fiscal year under this sec-*
12 *tion; or*

13 “(ii) *January 31 of each year.*

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

17 “(i) *100 percent of the amount of the*
18 *generic new animal drug sponsor fee pub-*
19 *lished for that fiscal year under subsection*
20 *(c) for an applicant with more than 6 ap-*
21 *proved abbreviated applications.*

22 “(ii) *75 percent of the amount of the*
23 *generic new animal drug sponsor fee pub-*
24 *lished for that fiscal year under subsection*
25 *(c) for an applicant with more than 1 and*

1 *fewer than 7 approved abbreviated applica-*
 2 *tions.*

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

8 “(b) *FEE AMOUNTS.*—Subject to subsections (c), (d),
 9 *(f), and (g), the fees required under subsection (a) shall be*
 10 *established to generate fee revenue amounts as follows:*

11 “(1) *TOTAL FEE REVENUES FOR APPLICATION*
 12 *FEES.*—The total fee revenues to be collected in abbrevi-
 13 *ated application fees under subsection (a)(1) shall*
 14 *be \$1,832,000 for fiscal year 2014, \$1,736,000 for fis-*
 15 *cal year 2015, \$1,857,000 for fiscal year 2016,*
 16 *\$1,984,000 for fiscal year 2017, and \$2,117,000 for*
 17 *fiscal year 2018.*

18 “(2) *TOTAL FEE REVENUES FOR PRODUCT*
 19 *FEES.*—The total fee revenues to be collected in ge-
 20 *neric new animal drug product fees under subsection*
 21 *(a)(2) shall be \$2,748,000 for fiscal year 2014,*
 22 *\$2,604,000 for fiscal year 2015, \$2,786,000 for fiscal*
 23 *year 2016, \$2,976,000 for fiscal year 2017, and*
 24 *\$3,175,000 for fiscal year 2018.*

1 “(3) *TOTAL FEE REVENUES FOR SPONSOR*
2 *FEES.*—*The total fee revenues to be collected in ge-*
3 *neric new animal drug sponsor fees under subsection*
4 *(a)(3) shall be \$2,748,000 for fiscal year 2014,*
5 *\$2,604,000 for fiscal year 2015, \$2,786,000 for fiscal*
6 *year 2016, \$2,976,000 for fiscal year 2017, and*
7 *\$3,175,000 for fiscal year 2018.*

8 “(c) *ANNUAL FEE SETTING; ADJUSTMENTS.*—

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

17 “(2) *WORKLOAD ADJUSTMENT.*—*The fee revenues*
18 *shall be adjusted each fiscal year after fiscal year*
19 *2014 to reflect changes in review workload. With re-*
20 *spect to such adjustment:*

21 “(A) *This adjustment shall be determined*
22 *by the Secretary based on a weighted average of*
23 *the change in the total number of abbreviated*
24 *applications for generic new animal drugs, man-*
25 *ufacturing supplemental abbreviated applica-*

1 *tions for generic new animal drugs, investiga-*
2 *tional generic new animal drug study submis-*
3 *sions, and investigational generic new animal*
4 *drug protocol submissions submitted to the Sec-*
5 *retary. The Secretary shall publish in the Fed-*
6 *eral Register the fees resulting from this adjust-*
7 *ment and the supporting methodologies.*

8 *“(B) Under no circumstances shall this*
9 *workload adjustment result in fee revenues for a*
10 *fiscal year that are less than the fee revenues for*
11 *that fiscal year established in subsection (b).*

12 *“(3) FINAL YEAR ADJUSTMENT.—For fiscal year*
13 *2018, the Secretary may, in addition to other adjust-*
14 *ments under this subsection, further increase the fees*
15 *under this section, if such an adjustment is necessary,*
16 *to provide for up to 3 months of operating reserves of*
17 *carryover user fees for the process for the review of ab-*
18 *breviated applications for generic new animal drugs*
19 *for the first 3 months of fiscal year 2019. If the Food*
20 *and Drug Administration has carryover balances for*
21 *the process for the review of abbreviated applications*
22 *for generic new animal drugs in excess of 3 months*
23 *of such operating reserves, then this adjustment shall*
24 *not be made. If this adjustment is necessary, then the*
25 *rationale for the amount of the increase shall be con-*

1 *tained in the annual notice setting fees for fiscal year*
2 *2018.*

3 “(4) *LIMIT.*—*The total amount of fees charged,*
4 *as adjusted under this subsection, for a fiscal year*
5 *may not exceed the total costs for such fiscal year for*
6 *the resources allocated for the process for the review*
7 *of abbreviated applications for generic new animal*
8 *drugs.*

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

14 “(e) *EFFECT OF FAILURE TO PAY FEES.*—*An abbrev-*
15 *viated application for a generic new animal drug submitted*
16 *by a person subject to fees under subsection (a) shall be con-*
17 *sidered incomplete and shall not be accepted for filing by*
18 *the Secretary until all fees owed by such person have been*
19 *paid. An investigational submission for a generic new ani-*
20 *mal drug that is submitted by a person subject to fees under*
21 *subsection (a) shall be considered incomplete and shall not*
22 *be accepted for review by the Secretary until all fees owed*
23 *by such person have been paid. The Secretary may dis-*
24 *continue review of any abbreviated application for a ge-*
25 *neric new animal drug, supplemental abbreviated applica-*

1 *tion for a generic new animal drug, or investigational sub-*
 2 *mission for a generic new animal drug from a person if*
 3 *such person has not submitted for payment all fees owed*
 4 *under this section by 30 days after the date upon which*
 5 *they are due.*

6 “(f) *ASSESSMENT OF FEES.*—

7 “(1) *LIMITATION.*—*Fees may not be assessed*
 8 *under subsection (a) for a fiscal year beginning after*
 9 *fiscal year 2008 unless appropriations for salaries*
 10 *and expenses of the Food and Drug Administration*
 11 *for such fiscal year (excluding the amount of fees ap-*
 12 *propriated for such fiscal year) are equal to or greater*
 13 *than the amount of appropriations for the salaries*
 14 *and expenses of the Food and Drug Administration*
 15 *for the fiscal year 2003 (excluding the amount of fees*
 16 *appropriated for such fiscal year) multiplied by the*
 17 *adjustment factor applicable to the fiscal year in-*
 18 *volved.*

19 “(2) *AUTHORITY.*—*If the Secretary does not as-*
 20 *sess fees under subsection (a) during any portion of*
 21 *a fiscal year because of paragraph (1) and if at a*
 22 *later date in such fiscal year the Secretary may assess*
 23 *such fees, the Secretary may assess and collect such*
 24 *fees, without any modification in the rate, for abbrev-*
 25 *viated applications, generic new animal drug spon-*

sors, and generic new animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

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

“(1) *IN GENERAL.*—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of abbreviated applications for generic new animal drugs.

“(2) *COLLECTIONS AND APPROPRIATION ACTS.*—

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

“(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount

1 *specified in appropriation Acts, or other-*
2 *wise made available for obligation for such*
3 *fiscal year; and*

4 “(ii) shall be available to defray in-
5 *creases in the costs of the resources allocated*
6 *for the process for the review of abbreviated*
7 *applications for generic new animal drugs*
8 *(including increases in such costs for an ad-*
9 *ditional number of full-time equivalent po-*
10 *sitions in the Department of Health and*
11 *Human Services to be engaged in such proc-*
12 *ess) over such costs, excluding costs paid*
13 *from fees collected under this section, for fis-*
14 *cal year 2008 multiplied by the adjustment*
15 *factor.*

16 “(B) COMPLIANCE.—*The Secretary shall be*
17 *considered to have met the requirements of sub-*
18 *paragraph (A)(ii) in any fiscal year if the costs*
19 *funded by appropriations and allocated for the*
20 *process for the review of abbreviated applications*
21 *for generic new animal drugs—*

22 “(i) are not more than 3 percent below
23 *the level specified in subparagraph (A)(ii);*
24 *or*

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

8 “(II) such costs are not more than 5
 9 percent below the level specified in subpara-
 10 graph (A)(ii).

11 “(C) *PROVISION FOR EARLY PAYMENTS.*—
 12 *Payment of fees authorized under this section for*
 13 *a fiscal year, prior to the due date for such fees,*
 14 *may be accepted by the Secretary in accordance*
 15 *with authority provided in advance in a prior*
 16 *year appropriations Act.*

17 “(3) *AUTHORIZATION OF APPROPRIATIONS.*—
 18 *There are authorized to be appropriated for fees under*
 19 *this section—*

20 “(A) \$7,328,000 for fiscal year 2014;

21 “(B) \$6,944,000 for fiscal year 2015;

22 “(C) \$7,429,000 for fiscal year 2016;

23 “(D) \$7,936,000 for fiscal year 2017; and

24 “(E) \$8,467,000 for fiscal year 2018;

1 *as adjusted to reflect adjustments in the total fee reve-*
2 *nues made under this section and changes in the total*
3 *amounts collected by abbreviated application fees, ge-*
4 *neric new animal drug sponsor fees, and generic new*
5 *animal drug product fees.*

6 “(4) *OFFSET.—If the sum of the cumulative*
7 *amount of fees collected under this section for the fis-*
8 *cal years 2014 through 2016 and the amount of fees*
9 *estimated to be collected under this section for fiscal*
10 *year 2017 exceeds the cumulative amount appro-*
11 *priated under paragraph (3) for the fiscal years 2014*
12 *through 2017, the excess amount shall be credited to*
13 *the appropriation account of the Food and Drug Ad-*
14 *ministration as provided in paragraph (1), and shall*
15 *be subtracted from the amount of fees that would oth-*
16 *erwise be authorized to be collected under this section*
17 *pursuant to appropriation Acts for fiscal year 2018.*

18 “(h) *COLLECTION OF UNPAID FEES.—In any case*
19 *where the Secretary does not receive payment of a fee as-*
20 *sessed under subsection (a) within 30 days after it is due,*
21 *such fee shall be treated as a claim of the United States*
22 *Government subject to subchapter II of chapter 37 of title*
23 *31, United States Code.*

24 “(i) *WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS,*
25 *AND REFUNDS.—To qualify for consideration for a waiver*

1 *or reduction under subsection (d), or for a refund of any*
 2 *fee collected in accordance with subsection (a), a person*
 3 *shall submit to the Secretary a written request for such*
 4 *waiver, reduction, or refund not later than 180 days after*
 5 *such fee is due.*

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

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

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

23 “(2) *ADJUSTMENT FACTOR.—The term ‘adjust-*
 24 *ment factor’ applicable to a fiscal year is the Con-*
 25 *sumer Price Index for all urban consumers (all items;*

1 *United States city average) for October of the pre-*
2 *ceding fiscal year divided by—*

3 *“(A) for purposes of subsection (f)(1), such*
4 *Index for October 2002; and*

5 *“(B) for purposes of subsection (g)(2)(A)(ii),*
6 *such Index for October 2007.*

7 *“(3) COSTS OF RESOURCES ALLOCATED FOR THE*
8 *PROCESS FOR THE REVIEW OF ABBREVIATED APPLI-*
9 *CATIONS FOR GENERIC NEW ANIMAL DRUGS.—The*
10 *term ‘costs of resources allocated for the process for the*
11 *review of abbreviated applications for generic new*
12 *animal drugs’ means the expenses in connection with*
13 *the process for the review of abbreviated applications*
14 *for generic new animal drugs for—*

15 *“(A) officers and employees of the Food and*
16 *Drug Administration, contractors of the Food*
17 *and Drug Administration, advisory committees*
18 *consulted with respect to the review of specific*
19 *abbreviated applications, supplemental abbrev-*
20 *viated applications, or investigational submis-*
21 *sions, and costs related to such officers, employ-*
22 *ees, committees, and contractors, including costs*
23 *for travel, education, and recruitment and other*
24 *personnel activities;*

1 “(B) management of information, and the
2 acquisition, maintenance, and repair of com-
3 puter resources;

4 “(C) leasing, maintenance, renovation, and
5 repair of facilities and acquisition, maintenance,
6 and repair of fixtures, furniture, scientific equip-
7 ment, and other necessary materials and sup-
8 plies; and

9 “(D) collecting fees under this section and
10 accounting for resources allocated for the review
11 of abbreviated applications, supplemental abbrevi-
12 ated applications, and investigational submis-
13 sions.

14 “(4) *FINAL DOSAGE FORM*.—The term ‘final dos-
15 age form’ means, with respect to a generic new ani-
16 mal drug product, a finished dosage form which is
17 approved for administration to an animal without
18 substantial further manufacturing. Such term in-
19 cludes generic new animal drug products intended for
20 mixing in animal feeds.

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

24 “(6) *GENERIC NEW ANIMAL DRUG PRODUCT*.—
25 The term ‘generic new animal drug product’ means

1 *each specific strength or potency of a particular ac-*
2 *tive ingredient or ingredients in final dosage form*
3 *marketed by a particular manufacturer or dis-*
4 *tributor, which is uniquely identified by the labeler*
5 *code and product code portions of the national drug*
6 *code, and for which an abbreviated application for a*
7 *generic new animal drug or a supplemental abbrev-*
8 *viated application has been approved.*

9 “(7) *GENERIC NEW ANIMAL DRUG SPONSOR.*—
10 *The term ‘generic new animal drug sponsor’ means*
11 *either an applicant named in an abbreviated applica-*
12 *tion for a generic new animal drug that has not been*
13 *withdrawn by the applicant and for which approval*
14 *has not been withdrawn by the Secretary, or a person*
15 *who has submitted an investigational submission for*
16 *a generic new animal drug that has not been termi-*
17 *nated or otherwise rendered inactive by the Secretary.*

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

22 “(A) *the filing of a claim for an investiga-*
23 *tional exemption under section 512(j) for a ge-*
24 *neric new animal drug intended to be the subject*

1 *of an abbreviated application or a supplemental*
2 *abbreviated application; or*

3 “(B) *the submission of information for the*
4 *purpose of enabling the Secretary to evaluate the*
5 *safety or effectiveness of a generic new animal*
6 *drug in the event of the filing of an abbreviated*
7 *application or supplemental abbreviated applica-*
8 *tion for such drug.*

9 “(9) *PERSON.*—*The term ‘person’ includes an af-*
10 *filiate thereof (as such term is defined in section*
11 *735(11)).*

12 “(10) *PROCESS FOR THE REVIEW OF ABBRE-*
13 *VIATED APPLICATIONS FOR GENERIC NEW ANIMAL*
14 *DRUGS.*—*The term ‘process for the review of abbre-*
15 *viated applications for generic new animal drugs’*
16 *means the following activities of the Secretary with*
17 *respect to the review of abbreviated applications, sup-*
18 *plemental abbreviated applications, and investiga-*
19 *tional submissions:*

20 “(A) *The activities necessary for the review*
21 *of abbreviated applications, supplemental abbre-*
22 *viated applications, and investigational submis-*
23 *sions.*

24 “(B) *The issuance of action letters which*
25 *approve abbreviated applications or supple-*

1 *mental abbreviated applications or which set*
2 *forth in detail the specific deficiencies in abbrev-*
3 *viated applications, supplemental abbreviated*
4 *applications, or investigational submissions and,*
5 *where appropriate, the actions necessary to place*
6 *such applications, supplemental applications, or*
7 *submissions in condition for approval.*

8 *“(C) The inspection of generic new animal*
9 *drug establishments and other facilities under-*
10 *taken as part of the Secretary’s review of pend-*
11 *ing abbreviated applications, supplemental ab-*
12 *breviated applications, and investigational sub-*
13 *missions.*

14 *“(D) Monitoring of research conducted in*
15 *connection with the review of abbreviated appli-*
16 *cations, supplemental abbreviated applications,*
17 *and investigational submissions.*

18 *“(E) The development of regulations and*
19 *policy related to the review of abbreviated appli-*
20 *cations, supplemental abbreviated applications,*
21 *and investigational submissions.*

22 *“(F) Development of standards for products*
23 *subject to review.*

24 *“(G) Meetings between the agency and the*
25 *generic new animal drug sponsor.*

1 “(H) *Review of advertising and labeling*
 2 *prior to approval of an abbreviated application*
 3 *or supplemental abbreviated application, but not*
 4 *after such application has been approved.*

5 “(11) *SUPPLEMENTAL ABBREVIATED APPLICA-*
 6 *TION FOR GENERIC NEW ANIMAL DRUG.—The terms*
 7 *‘supplemental abbreviated application for a generic*
 8 *new animal drug’ and ‘supplemental abbreviated ap-*
 9 *plication’ mean a request to the Secretary to approve*
 10 *a change in an approved abbreviated application.”.*

11 **SEC. 203. REAUTHORIZATION; REPORTING REQUIREMENTS.**

12 *Section 742 of the Federal Food, Drug, and Cosmetic*
 13 *Act (21 U.S.C. 379j–22) is amended to read as follows:*

14 **“SEC. 742. REAUTHORIZATION; REPORTING REQUIRE-**
 15 **MENTS.**

16 “(a) *PERFORMANCE REPORTS.—Beginning with fiscal*
 17 *year 2014, not later than 120 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 Health, Education, Labor, and Pensions of the Senate,*
 21 *and the Committee on Energy and Commerce of the House*
 22 *of Representatives a report concerning the progress of the*
 23 *Food and Drug Administration in achieving the goals iden-*
 24 *tified in the letters described in section 201(b) of the Animal*
 25 *Generic Drug User Fee Amendments of 2013 toward expe-*

1 *diting the generic new animal drug development process*
2 *and the review of abbreviated applications for generic new*
3 *animal drugs, supplemental abbreviated applications for*
4 *generic new animal drugs, and investigational submissions*
5 *for generic new animal drugs during such fiscal year.*

6 “(b) *FISCAL REPORT.*—*Beginning with fiscal year*
7 *2014, not later than 120 days after the end of each fiscal*
8 *year during which fees are collected under this part, the*
9 *Secretary shall prepare and submit to the Committee on*
10 *Health, Education, Labor, and Pensions of the Senate and*
11 *the Committee on Energy and Commerce of the House of*
12 *Representatives a report on the implementation of the au-*
13 *thority for such fees during such fiscal year and the use,*
14 *by the Food and Drug Administration, of the fees collected*
15 *during such fiscal year for which the report is made.*

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

20 “(d) *REAUTHORIZATION.*—

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

1 *after fiscal year 2018, and for the reauthorization of*
2 *this part for such fiscal years, the Secretary shall con-*
3 *sult with—*

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

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

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

9 “(D) *veterinary professionals;*

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

12 “(F) *the regulated industry.*

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

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

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

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

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

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

11 “(4) *PUBLIC REVIEW OF RECOMMENDATIONS*.—
12 After negotiations with the regulated industry, the
13 Secretary shall—

14 “(A) present the recommendations developed
15 under paragraph (1) to the congressional com-
16 mittees specified in such paragraph;

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

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

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

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

4 “(5) *TRANSMITTAL OF RECOMMENDATIONS.*—Not
5 later than January 15, 2018, the Secretary shall
6 transmit to Congress the revised recommendations
7 under paragraph (4), a summary of the views and
8 comments received under such paragraph, and any
9 changes made to the recommendations in response to
10 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 Sec-
15 retary shall make publicly available, on the
16 Internet Web site of the Food and Drug Admin-
17 istration, minutes of all negotiation meetings
18 conducted under this subsection between the Food
19 and Drug Administration and the regulated in-
20 dustry.

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. 204. SAVINGS CLAUSE.**

4 *Notwithstanding the amendments made by this title,*
5 *part 5 of subchapter C of chapter VII of the Federal Food,*
6 *Drug, and Cosmetic Act, as in effect on the day before the*
7 *date of enactment of this title, shall continue to be in effect*
8 *with respect to abbreviated applications for a generic new*
9 *animal drug and supplemental abbreviated applications for*
10 *a generic new animal drug (as defined in such part as of*
11 *such day) that on or after October 1, 2008, but before Octo-*
12 *ber 1, 2013, were accepted by the Food and Drug Adminis-*
13 *tration for filing with respect to assessing and collecting*
14 *any fee required by such part for a fiscal year prior to fiscal*
15 *year 2014.*

16 **SEC. 205. EFFECTIVE DATE.**

17 *The amendments made by this title shall take effect*
18 *on October 1, 2013, or the date of enactment of this title,*
19 *whichever is later, except that fees under part 5 of sub-*
20 *chapter C of chapter VII of the Federal Food, Drug, and*
21 *Cosmetic Act, as amended by this title, shall be assessed for*
22 *all abbreviated applications for a generic new animal drug*
23 *and supplemental abbreviated applications for a generic*
24 *new animal drug received on or after October 1, 2013, re-*
25 *gardless of the date of enactment of this title.*

1 **SEC. 206. SUNSET DATES.**

2 (a) *AUTHORIZATION*.—Section 741 of the Federal
3 *Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–21) shall
4 *cease to be effective October 1, 2018.*

5 (b) *REPORTING REQUIREMENTS*.—Section 742 of the
6 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
7 22) shall *cease to be effective January 31, 2019.*

8 (c) *PREVIOUS SUNSET PROVISION*.—

9 (1) *IN GENERAL*.—Section 204 of the *Animal Ge-*
10 *neric Drug User Fee Act of 2008* (Public Law 110–
11 316) *is repealed.*

12 (2) *CONFORMING AMENDMENT*.—Public Law
13 110–316 (122 Stat. 3509) *is amended in the table of*
14 *contents in section 1, by striking the item relating to*
15 *section 204.*

Amend the title so as to read: “A bill to amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.”.

Union Calendar No. 135

113TH CONGRESS
1ST Session

H. R. 1407

[Report No. 113-188]

A BILL

To amend the Federal Food, Drug, and Cosmetic
Act to reauthorize user fee programs relating to
new animal drugs.

AUGUST 2, 2013

Reported with amendments, committed to the Committee
of the Whole House on the State of the Union, and or-
dered to be printed