

113TH CONGRESS
1ST SESSION

H. R. 1408

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 9, 2013

Mr. GARDNER (for himself, Mr. SHIMKUS, 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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs 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; FINDING.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Animal Generic Drug User Fee Amendments of 2013”.

6 (b) FINDING.—The fees authorized by this Act will
7 be dedicated toward expediting the generic new animal
8 drug development process and the review of abbreviated
9 applications for generic new animal drugs, supplemental

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

9 **SEC. 2. AUTHORITY TO ASSESS AND USE GENERIC NEW**
10 **ANIMAL DRUG FEES.**

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

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 (c) for such an application.

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

4 “(C) EXCEPTIONS.—

5 “(i) PREVIOUSLY FILED APPLICA-
6 TION.—If an abbreviated application was
7 submitted by a person that paid the fee for
8 such application, was accepted for filing,
9 and was not approved or was withdrawn
10 (without a waiver or refund), the submis-
11 sion of an abbreviated application for the
12 same product by the same person (or the
13 person’s licensee, assignee, or successor)
14 shall not be subject to a fee under sub-
15 paragraph (A).

16 “(ii) CERTAIN ABBREVIATED APPLICA-
17 TIONS INVOLVING COMBINATION ANIMAL
18 DRUGS.—An abbreviated application for an
19 animal drug described in section 512(d)(4)
20 and submitted on or after October 1, 2013,
21 shall be subject to a fee equal to 50 per-
22 cent of the amount of the abbreviated ap-
23 plication fee established in subsection (c).

24 “(D) REFUND OF FEE IF APPLICATION RE-
25 FUSED FOR FILING.—The Secretary shall re-

1 fund 75 percent of the fee paid under subpara-
2 graph (B) for any abbreviated application which
3 is refused for filing.

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

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

17 “(A) IN GENERAL.—Each person—

18 “(i) who is named as the applicant in
19 an abbreviated application or supplemental
20 abbreviated application for a generic new
21 animal drug product which has been sub-
22 mitted for listing under section 510; and

23 “(ii) who, after September 1, 2008,
24 had pending before the Secretary an abbrev-

1 viated application or supplemental abbrevi-
2 viated application,
3 shall pay for each such generic new animal
4 drug product the annual fee established in sub-
5 section (c).

6 “(B) PAYMENT; FEE DUE DATE.—Such fee
7 shall be payable for the fiscal year in which the
8 generic new animal drug product is first sub-
9 mitted for listing under section 510, or is sub-
10 mitted for relisting under section 510 if the ge-
11 neric new animal drug product has been with-
12 drawn from listing and relisted. After such fee
13 is paid for that fiscal year, such fee shall be due
14 each subsequent fiscal year that the product re-
15 mains listed, upon the later of—

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

21 “(ii) January 31 of each year.

22 “(C) LIMITATION.—Such fee shall be paid
23 only once for each generic new animal drug
24 product for a fiscal year in which the fee is pay-
25 able.

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 generic new animal
13 drug sponsor fee as established under sub-
14 section (c).

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

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

22 “(ii) January 31 of each year.

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

1 “(i) 100 percent of the amount of the
2 generic new animal drug sponsor fee pub-
3 lished for that fiscal year under subsection
4 (c) for an applicant with more than 6 ap-
5 proved abbreviated applications.

6 “(ii) 75 percent of the amount of the
7 generic new animal drug sponsor fee pub-
8 lished for that fiscal year under subsection
9 (c) for an applicant with more than 1 and
10 fewer than 7 approved abbreviated applica-
11 tions.

12 “(iii) 50 percent of the amount of the
13 generic new animal drug sponsor fee pub-
14 lished for that fiscal year under subsection
15 (c) for an applicant with 1 or fewer ap-
16 proved abbreviated applications.

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

20 “(1) TOTAL FEE REVENUES FOR APPLICATION
21 FEES.—The total fee revenues to be collected in ab-
22 breviated application fees under subsection (a)(1)
23 shall be \$1,832,000 for fiscal year 2014, \$1,736,000
24 for fiscal year 2015, \$1,857,000 for fiscal year

1 2016, \$1,984,000 for fiscal year 2017, and
2 \$2,117,000 for fiscal year 2018.

3 “(2) TOTAL FEE REVENUES FOR PRODUCT
4 FEES.—The total fee revenues to be collected in ge-
5 neric new animal drug product fees under subsection
6 (a)(2) shall be \$2,748,000 for fiscal year 2014,
7 \$2,604,000 for fiscal year 2015, \$2,786,000 for fis-
8 cal year 2016, \$2,976,000 for fiscal year 2017, and
9 \$3,175,000 for fiscal year 2018.

10 “(3) TOTAL FEE REVENUES FOR SPONSOR
11 FEES.—The total fee revenues to be collected in ge-
12 neric new animal drug sponsor fees under subsection
13 (a)(3) shall be \$2,748,000 for fiscal year 2014,
14 \$2,604,000 for fiscal year 2015, \$2,786,000 for fis-
15 cal year 2016, \$2,976,000 for fiscal year 2017, and
16 \$3,175,000 for fiscal year 2018.

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

18 “(1) ANNUAL FEE SETTING.—The Secretary
19 shall establish, 60 days before the start of each fis-
20 cal year beginning after September 30, 2008, for
21 that fiscal year, abbreviated application fees, generic
22 new animal drug sponsor fees, and generic new ani-
23 mal drug product fees, based on the revenue
24 amounts established under subsection (b) and the
25 adjustments provided under this subsection.

1 “(2) WORKLOAD ADJUSTMENT.—The fee reve-
2 nues shall be adjusted each fiscal year after fiscal
3 year 2014 to reflect changes in review workload.

4 With respect to such adjustment:

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

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

23 “(3) FINAL YEAR ADJUSTMENT.—For fiscal
24 year 2018, the Secretary may, in addition to other
25 adjustments under this subsection, further increase

1 the fees under this section, if such an adjustment is
2 necessary, to provide for up to 3 months of oper-
3 ating reserves of carryover user fees for the process
4 for the review of abbreviated applications for generic
5 new animal drugs for the first 3 months of fiscal
6 year 2019. If the Food and Drug Administration
7 has carryover balances for the process for the review
8 of abbreviated applications for generic new animal
9 drugs in excess of 3 months of such operating re-
10 serves, then this adjustment shall not be made. If
11 this adjustment is necessary, then the rationale for
12 the amount of the increase shall be contained in the
13 annual notice setting fees for fiscal year 2018.

14 “(4) LIMIT.—The total amount of fees charged,
15 as adjusted under this subsection, for a fiscal year
16 may not exceed the total costs for such fiscal year
17 for the resources allocated for the process for the re-
18 view of abbreviated applications for generic new ani-
19 mal drugs.

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

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

18 “(f) ASSESSMENT OF FEES.—

19 “(1) LIMITATION.—Fees may not be assessed
20 under subsection (a) for a fiscal year beginning after
21 fiscal year 2008 unless appropriations for salaries
22 and expenses of the Food and Drug Administration
23 for such fiscal year (excluding the amount of fees
24 appropriated for such fiscal year) are equal to or
25 greater than the amount of appropriations for the

1 salaries and expenses of the Food and Drug Admin-
2 istration for the fiscal year 2003 (excluding the
3 amount of fees appropriated for such fiscal year)
4 multiplied by the adjustment factor applicable to the
5 fiscal year involved.

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

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

18 “(1) IN GENERAL.—Subject to paragraph
19 (2)(C), fees authorized under subsection (a) shall be
20 collected and available for obligation only to the ex-
21 tent and in the amount provided in advance in ap-
22 propriations Acts. Such fees are authorized to be ap-
23 propriated to remain available until expended. Such
24 sums as may be necessary may be transferred from
25 the Food and Drug Administration salaries and ex-

1 penses appropriation account without fiscal year lim-
2 itation to such appropriation account for salary and
3 expenses with such fiscal year limitation. The sums
4 transferred shall be available solely for the process
5 for the review of abbreviated applications for generic
6 new animal drugs.

7 “(2) COLLECTIONS AND APPROPRIATION
8 ACTS.—

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

11 “(i) subject to subparagraph (C), shall
12 be collected and available in each fiscal
13 year in an amount not to exceed the
14 amount specified in appropriation Acts, or
15 otherwise made available for obligation for
16 such fiscal year; and

17 “(ii) shall be available to defray in-
18 creases in the costs of the resources allo-
19 cated for the process for the review of ab-
20 bre viated applications for generic new ani-
21 mal drugs (including increases in such
22 costs for an additional number of full-time
23 equivalent positions in the Department of
24 Health and Human Services to be engaged
25 in such process) over such costs, excluding

1 costs paid from fees collected under this
2 section, for fiscal year 2008 multiplied by
3 the adjustment factor.

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

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

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

20 “(II) such costs are not more than 5
21 percent below the level specified in sub-
22 paragraph (A)(ii).

23 “(C) PROVISION FOR EARLY PAYMENTS.—
24 Payment of fees authorized under this section
25 for a fiscal year, prior to the due date for such

1 fees, may be accepted by the Secretary in ac-
2 cordance with authority provided in advance in
3 a prior year appropriations Act.

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

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

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

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

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

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

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

17 “(4) OFFSET.—If the sum of the cumulative
18 amount of fees collected under this section for the
19 fiscal years 2014 through 2016 and the amount of
20 fees estimated to be collected under this section for
21 fiscal year 2017 exceeds the cumulative amount ap-
22 propriated under paragraph (3) for the fiscal years
23 2014 through 2017, the excess amount shall be
24 credited to the appropriation account of the Food
25 and Drug Administration as provided in paragraph

1 (1), and shall be subtracted from the amount of fees
2 that would otherwise be authorized to be collected
3 under this section pursuant to appropriation Acts
4 for fiscal year 2018.

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

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

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

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

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

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

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

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

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

1 viated applications for generic new animal drugs
2 for—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **SEC. 3. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

4 **“SEC. 742. REAUTHORIZATION; REPORTING REQUIRE-**
5 **MENTS.**

6 “(a) PERFORMANCE REPORTS.—Beginning with fis-
7 cal year 2014, not later than 120 days after the end of
8 each fiscal year during which fees are collected under this
9 part, the Secretary shall prepare and submit to the Com-
10 mittee on Health, Education, Labor, and Pensions of the
11 Senate, and the Committee on Energy and Commerce of
12 the House of Representatives a report concerning the
13 progress of the Food and Drug Administration in achiev-
14 ing the goals identified in the letters described in section
15 1(b) of the Animal Generic Drug User Fee Amendments
16 of 2013 toward expediting the generic new animal drug
17 development process and the review of abbreviated appli-
18 cations for generic new animal drugs, supplemental abbrevi-
19 ated applications for generic new animal drugs, and in-
20 vestigational submissions for generic new animal drugs
21 during such fiscal year.

22 “(b) FISCAL REPORT.—Beginning with fiscal year
23 2014, not later than 120 days after the end of each fiscal
24 year during which fees are collected under this part, the
25 Secretary shall prepare and submit to the Committee on
26 Health, Education, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the House
2 of Representatives a report on the implementation of the
3 authority for such fees during such fiscal year and the
4 use, by the Food and Drug Administration, of the fees
5 collected during such fiscal year for which the report is
6 made.

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

11 “(d) REAUTHORIZATION.—

12 “(1) CONSULTATION.—In developing rec-
13 ommendations to present to Congress with respect to
14 the goals, and plans for meeting the goals, for the
15 process for the review of abbreviated applications for
16 generic new animal drugs for the first 5 fiscal years
17 after fiscal year 2018, and for the reauthorization of
18 this part for such fiscal years, the Secretary shall
19 consult with—

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

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

24 “(C) scientific and academic experts;

25 “(D) veterinary professionals;

1 “(E) representatives of patient and con-
2 sumer advocacy groups; and

3 “(F) the regulated industry.

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

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

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

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

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

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

1 their suggestions for changes to this part as ex-
2 pressed under paragraph (2).

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

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

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

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

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

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

20 “(5) TRANSMITTAL OF RECOMMENDATIONS.—
21 Not later than January 15, 2018, the Secretary
22 shall transmit to Congress the revised recommenda-
23 tions under paragraph (4), a summary of the views
24 and comments received under such paragraph, and

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

3 “(6) MINUTES OF NEGOTIATION MEETINGS.—

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

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

19 **SEC. 4. SAVINGS CLAUSE.**

20 Notwithstanding the amendments made by this Act,
21 part 5 of subchapter C of chapter VII of the Federal Food,
22 Drug, and Cosmetic Act, as in effect on the day before
23 the date of enactment of this Act, shall continue to be
24 in effect with respect to abbreviated applications for a ge-
25 neric new animal drug and supplemental abbreviated ap-

1 plications for a generic new animal drug (as defined in
2 such part as of such day) that on or after October 1, 2008,
3 but before October 1, 2013, were accepted by the Food
4 and Drug Administration for filing with respect to assess-
5 ing and collecting any fee required by such part for a fiscal
6 year prior to fiscal year 2014.

7 **SEC. 5. EFFECTIVE DATE.**

8 The amendments made by this Act shall take effect
9 on October 1, 2013, or the date of enactment of this Act,
10 whichever is later, except that fees under part 5 of sub-
11 chapter C of chapter VII of the Federal Food, Drug, and
12 Cosmetic Act, as amended by this Act, shall be assessed
13 for all abbreviated applications for a generic new animal
14 drug and supplemental abbreviated applications for a ge-
15 neric new animal drug received on or after October 1,
16 2013, regardless of the date of enactment of this Act.

17 **SEC. 6. SUNSET DATES.**

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

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

24 (c) **PREVIOUS SUNSET PROVISION.**—

1 (1) IN GENERAL.—Section 204 of the Animal
2 Generic Drug User Fee Act of 2008 (Public Law
3 110–316) is repealed.

4 (2) CONFORMING AMENDMENT.—The Animal
5 Generic Drug User Fee Act of 2008 (Public Law
6 110–316) is amended in the table of contents in sec-
7 tion 1, by striking the item relating to section 204.

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