Proposed AGDUFA II Provisions of the Federal Food, Drug, and Cosmetic Act

SEC. 741. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

(a) TYPES OF FEES.—Beginning with respect to fiscal year 2009, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) ABBREVIATED APPLICATION FEE.—

(A) IN GENERAL.—Each person that submits, on or after July 1, 2008, an abbreviated application for a generic new animal drug shall be subject to a fee as established in subsection (c) for such an application.

(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the abbreviated application.

(C) EXCEPTIONS.—

(1) FOR PREVIOUSLY FILED APPLICATION.—If an abbreviated application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an abbreviated application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(2) FOR CERTAIN ABBREVIATED APPLICATIONS INVOLVING COMBINATION ANIMAL DRUGS.—An abbreviated application which is subject to the criteria in section 512(d)(4) and submitted on or after October 1, 2013 shall be subject to a fee equal to 50 percent of the amount of the abbreviated application fee established in subsection (c).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any abbreviated application which is refused for filing.

(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an abbreviated application is withdrawn after the application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the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 submitted 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 application, a supplemental abbreviated application, or an investigational submission,

shall be assessed an annual sponsor fee as established under subsection (c).

(B) PAYMENT; FEE DUE DATE.—Such fee shall be due each fiscal year 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) AMOUNT OF FEE.—Each generic new animal drug sponsor shall pay only 1 such fee each fiscal year, as follows:

(i) 100 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 6 approved abbreviated applications.

(ii) 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

(iii) 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with 1 or fewer approved abbreviated applications.

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

(1) TOTAL FEE REVENUES FOR APPLICATION FEES.—The total fee revenues to be collected in abbreviated application fees under subsection (a)(1) shall be $1,832,000 for fiscal year 2014, $1,736,000 for fiscal year 2015, $1,857,000 for fiscal year 2016, $1,984,000 for fiscal year 2017, and $2,117,000 for fiscal year 2018.

(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in generic new animal drug product fees under subsection (a)(2) shall be $2,748,000 for fiscal year 2014, $2,604,000 for fiscal year 2015, $2,786,000 for fiscal year 2016, $2,976,000 for fiscal year 2017, and $3,175,000 for fiscal year 2018.

(3) TOTAL FEE REVENUES FOR SPONSOR FEES.—The total fee revenues to be collected in generic new animal drug sponsor fees under subsection (a)(3) shall be $2,748,000 for fiscal year 2014, $2,604,000 for

fiscal year 2015, $2,786,000 for fiscal year 2016, $2,976,000 for fiscal year 2017, and $3,175,000 for fiscal year 2018.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2008, for that fiscal year, abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees, based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

(2) WORKLOAD ADJUSTMENT.—The fee revenues shall be adjusted each fiscal year after fiscal year 2014 to reflect changes in review workload. With respect to such adjustment:

(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

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

(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2018, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of fiscal year 2019. If the Food and Drug Administration has carryover balances for the process for the review of abbreviated applications for generic new animal drugs in excess of 3 months of such operating reserves, then this adjustment shall not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2018.

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

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

(e) EFFECT OF FAILURE TO PAY FEES.—An abbreviated application for a generic new animal drug submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational submission for a generic new animal drug that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

(f) ASSESSMENT OF FEES.—

(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for abbreviated applications, generic new animal drug sponsors, 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 specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2008 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of abbreviated applications for generic new animal drugs—

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

(ii)

(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following 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.—There are authorized to be appropriated for fees under this section—

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

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

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

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

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

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees.

(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 exceeds the cumulative amount appropriated under 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.

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

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

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of abbreviated applications for generic new animal drugs, be reduced to offset the number of officers, employees, and advisory committees so engaged.

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

(1) ABBREVIATED APPLICATION FOR A GENERIC NEW ANIMAL DRUG.—The terms ‘abbreviated application for a generic new animal drug’ and ‘abbreviated application’ mean an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2). Such term does not include a supplemental abbreviated application for a generic new animal drug.

(2) ADJUSTMENT FACTOR.—The term ‘adjustment factor’ applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by—

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

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

(3) COSTS OF RESOURCES ALLOCATED FOR THE PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—The term ‘costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs’ means the expenses in connection with the process for the review of abbreviated applications for generic new animal drugs for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees under this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(4) FINAL DOSAGE FORM.—The term ‘final dosage form’ means, with respect to a generic new animal drug product, a finished dosage form which is

approved for administration to an animal without substantial further manufacturing. Such term includes generic new animal drug products intended for mixing in animal feeds.

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

(6) GENERIC NEW ANIMAL DRUG PRODUCT.—The term ‘generic new animal drug product’ means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or a supplemental abbreviated application has been approved.

(7) GENERIC NEW ANIMAL DRUG SPONSOR.—The term ‘generic new animal drug sponsor’ means either an applicant named in an abbreviated application for a generic new animal drug that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive by the Secretary.

(8) INVESTIGATIONAL SUBMISSION FOR A GENERIC NEW ANIMAL DRUG.—The terms investigational submission for a generic new animal drug’ and ‘investigational submission’ mean—

(A) the filing of a claim for an investigational exemption under section 512(j) for a generic new animal drug intended to be the subject of an abbreviated application or a supplemental abbreviated application; or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of a generic new animal drug in the event of the filing of an abbreviated application or supplemental abbreviated application for such drug.

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

(10) PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—The term ‘process for the review of abbreviated applications for generic new animal drugs’ means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:

(A) The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(B) The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval.

(C) The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary's review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(D) Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(E) The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(F) Development of standards for products subject to review.

G) Meetings between the agency and the generic new animal drug sponsor.

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

(11) SUPPLEMENTAL ABBREVIATED APPLICATION FOR GENERIC NEW ANIMAL DRUG.—The terms 'supplemental abbreviated application for a generic new animal drug' and 'supplemental abbreviated application' mean a request to the Secretary to approve a change in an approved abbreviated application.

SEC. 742. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORTS.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and

Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(3) of the Animal Generic Drug User Fee Act of 2013 toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs during such fiscal year.

(b) FISCAL REPORT.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

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

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of abbreviated applications for generic new animal drugs for the first 5 fiscal years after fiscal year 2018, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

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

(C) scientific and academic experts;

(D) veterinary professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry. and their suggestions for changes to this part as expressed under paragraph (2).

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

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

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

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

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

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2018, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to

Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

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

AGDUFA II provisions not amending the Federal Food, Drug, and Cosmetic Act

SEC. [*xxx*]. SAVINGS CLAUSE.

Notwithstanding section 204 of the Animal Generic Drug User Fee Act of 2008, and notwithstanding the amendments made by this Act, part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of enactment of this Act, shall continue to be in effect with respect to abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug (as defined in such part as of such day) that on or after October 1, 2008, but before October 1, 2013, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2014.

SEC. [*xxx*]. EFFECTIVE DATE.

The amendments made by sections [xxx-yyy] shall take effect on October 1, 2013, and fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall be assessed for all abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after such date, regardless of the date of enactment of this Act.

SEC. *[xxx]*. SUNSET DATES.

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

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

(c) Previous Sunset Provision.—

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

(2) CONFORMING AMENDMENT.—Public Law 110-316 is amended in the table of contents in section 1, by striking the item relating to section 204.