110TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
110–805

ANIMAL GENERIC DRUG USER FEE ACT OF 2008

JULY 30, 2008.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. DINGELL, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 6433]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 6433) to amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to generic new animal drugs, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; REFERENCES.

(a) SHORT TITLE.—This Act may be cited as the "Animal Generic Drug User Fee Act of 2008".

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

SEC. 2. FINDINGS.

Congress finds as follows:

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

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

(3) The fees authorized by this Act will be dedicated 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 as set forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

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

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

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

"PART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS

"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 (b) for such an application.

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

"(C) EXCEPTION 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).

"(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.—Each person—

"(A) 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

"(B) 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 (b). 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 payable on or before January 31 of each year. 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 fee established under subsection (b). The fee shall be paid on or before January 31 of each year.

"(B) 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)(3) 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)(3) 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)(3) for an applicant with 1 or fewer approved abbreviated applications.

"(b) FEE AMOUNTS.—Except as provided in subsection (a)(1) and 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 $1,449,000 for fiscal year 2009, $1,532,000 for fiscal year 2010, $1,619,000 for fiscal year 2011, $1,712,000 for fiscal year 2012, and $1,809,000 for fiscal year 2013.

"(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 $1,691,000 for fiscal year 2009, $1,787,000 for fiscal year 2010, $1,889,000 for fiscal year 2011, $1,997,000 for fiscal year 2012, and $2,111,000 for fiscal year 2013.

"(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 $1,691,000 for fiscal year 2009, $1,787,000 for fiscal year 2010, $1,889,000 for fiscal year 2011, $1,997,000 for fiscal year 2012, and $2,111,000 for fiscal year 2013.

"(c) ADJUSTMENTS.—

"(1) WORKLOAD ADJUSTMENT.—The fee revenues shall be adjusted each fiscal year after fiscal year 2009 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).

"(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2013, the Secretary may further increase the fees to provide for up to 3 months of operating reserves of car-

ryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of fiscal year 2014. 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 2013.

"(3) 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.

"(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.—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) shall be retained 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 only be collected and 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).

"(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

"(A) $4,831,000 for fiscal year 2009;

"(B) $5,106,000 for fiscal year 2010;

"(C) $5,397,000 for fiscal year 2011;

"(D) $5,706,000 for fiscal year 2012; and

"(E) $6,031,000 for fiscal year 2013;

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 2009 through 2011 and the amount of fees estimated to be collected under this section for fiscal year 2012 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2009 through 2012, 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 2013.

"(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 for a 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 incurred 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. 4. ACCOUNTABILITY AND REPORTS.

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

"SEC. 742. REAUTHORIZATION; REPORTING REQUIREMENTS.

"(a) PERFORMANCE REPORTS.—Beginning with fiscal year 2009, not later than 60 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 2(3) of the Animal Generic Drug User Fee Act of 2008 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 2009, 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 2013, 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.

"(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, 2013, 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.".

SEC. 5. SUNSET DATES.

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

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

PURPOSE AND SUMMARY

The purpose of H.R. 6433, the Animal Generic Drug User Fee Act of 2008, is to establish a program of fees for the review of generic animal drug submissions and to improve the timeliness and predictability of the process for generic animal drug submissions.

BACKGROUND AND NEED FOR LEGISLATION

H.R. 6433 would establish a program of fees relating to generic new animal drugs. Using the Animal Drug User Fee Act of 2003 (ADUFA) as a model, the Animal Generic Drug User Fee Act of 2008 (AGDUFA) would provide funding for increased review of generic animal drug submissions, for training and development of staff members, and for refining business processes and developing policies to allow more efficient review of generic animal drug submissions.

In Congressional testimony in June 2008, the Food and Drug Administration (FDA) reported that in fiscal year 2007, the average review time for generic animal drug submissions was 570 days and that there was a backlog of 446 of these submissions, almost double the number in fiscal year (FY) 2000. Section 512(c)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires FDA to review and act on these submissions within 180 days of submission.

In order to alleviate this backlog, a user fee for generic animal drug submissions is proposed, along with relevant performance goals. Under the AGDUFA user-fee proposal, FDA would agree to meet review performance goals to improve the timeliness and predictability of the animal generic drug review process. These performance goals are intended to achieve progressive yearly improvements, shortening the time for FDA to review and act on submissions with each fiscal year. By the fifth and final year of the proposed user fees, FDA would agree to review and act on 90 percent

of the sentinel submission types within specified timeframes. Currently, FDA's review of generic animal drug submissions is funded entirely through appropriations.

The AGDUFA proposal has many similarities to the proposal for ADUFA II (H.R. 6432, the Animal Drug User Fee Amendments of 2008), such as comparable fee triggers, fee-setting requirements, workload adjustments, and reporting requirements. The major differences are that AGDUFA does not allow FDA to collect establishment fees, and FDA may only waive or reduce fees if the drug is intended for a minor use or minor species indication. Also, similar to the ADUFA II proposal, the AGDUFA proposal has fixed annual increases instead of the inflation adjuster used for the original ADUFA.

AGDUFA authorizes the collection of fees for FY 2009 to 2013 in the following amounts: $4,831,000 for FY 2009; $5,106,000 for FY 2010; $5,397,000 for FY 2011; $5,706,000 for FY 2012; and $6,031,000 for FY 2013. Fees are included for abbreviated applications, generic new animal drug products, and generic new animal drug sponsors.

HEARINGS

On June 5, 2008, the Subcommittee on Health held a hearing on "Committee Prints on Administration Legislative Proposals on the Animal Drug User Fee Act Amendments of 2008 and the Animal Generic Drug User Fee Act of 2008." The Subcommittee received testimony from Bernadette Dunham, D.V.M., Ph.D., Director, Center for Veterinary Medicine, Food and Drug Administration. Dr. Dunham was accompanied by Steven Vaughn, D.V.M., Director, Office of New Animal Drug Evaluation, and David Wardrop, Jr., Director, Office of Management. The Subcommittee also received testimony from Richard A. Carnevale, V.M.D., Vice President of Regulatory, Scientific, and International Affairs, Animal Health Institute; Ms. Stephanie Batliner, Chairperson, Generic Animal Drug Alliance, Director, Pre-Market Regulatory Affairs, IVX Animal Health, Inc.; and Mr. Robert Martin, Executive Director, Pew Commission on Industrial Farm Animal Production.

COMMITTEE CONSIDERATION

On Wednesday, July 9, 2008, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 6433 to the full Committee for consideration, by a voice vote. On Wednesday, July 16, 2008, the full Committee met in open markup session and ordered H.R. 6433 favorably reported to the House, amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. No record votes were taken on amendments or in connection with ordering H.R. 6433 reported to the House. A motion by Mr. Dingell to order H.R. 6433 favorably reported to the House, amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the oversight findings of the Committee regarding H.R. 6433 are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objectives of H.R. 6433 are to improve the timeliness and predictability of the review process for generic animal drug submissions and to improve the timeliness and predictability of the process for generic animal drug submissions.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 6433 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS AND TAX AND TARIFF BENEFITS

Regarding compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 6433 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate on H.R. 6433 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate on H.R. 6433 provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 28, 2008.

Hon. JOHN D. DINGELL,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 6433, the Animal Generic Drug User Fee Act of 2008.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

ROBERT A. SUNSHINE
(For Peter R. Orszag, Director).

Enclosure.

H.R. 6433 Animal Generic Drug User Fee Act of 2008

Summary: H.R. 6433 would amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration (FDA) to collect fees to cover the cost for certain activities to expedite the development and marketing of generic new drugs for use in animals. Fees would supplement appropriated funds to cover FDA's cost associated with reviewing certain marketing applications and investigational submissions for such drugs. Those fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts.

CBO estimates that implementing H.R. 6433 would reduce discretionary outlays, on net, by $1 million over the 2009–2013 period, assuming the necessary authorities are provided in appropriation acts. Enacting the bill would not affect direct spending or revenues.

H.R. 6433 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

The bill's requirement that sponsors of generic new drugs for use in animals to pay certain fees to FDA would be a private-sector mandate as defined in UMRA. However, CBO estimates that the direct cost of complying with this requirement would not exceed the annual thresholds established by UMRA for private-sector mandates ($136 million in 2008, adjusted annually for inflation).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 6433 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2009	2010	2011	2012	2013	2009–2013
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Food and Drug Administration (FDA):						
Collection of User Fees:						
Estimated Authorization Level	−5	−5	−5	−6	−8	−29
Estimated Outlays	−5	−5	−5	−6	−8	−29
Spending of User Fees:						
Estimated Authorization Level	5	5	5	6	8	29
Estimated Outlays	3	6	6	6	6	27
Administrative Expenses:						
Estimated Authorization Level	*	*	*	*	*	1
Estimated Outlays	*	*	*	*	*	1
Net Effect on Spending by FDA:						
Estimated Authorization Level	*	*	*	*	*	1
Estimated Outlays	−2	1	*	*	−1	−1

Note: * = less than $500,000. Components may not sum to totals because of rounding.

Basis of estimate: For this estimate, CBO assumes that H.R. 6433 will be enacted near the start of fiscal year 2009, that the full amounts authorized will be collected and appropriated for each year, and that outlays will follow historical patterns for similar activities. Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 6433 would reduce discretionary outlays, on net, by $1 million over the 2009–2013 period, primarily because the spending of authorized fees slightly lags behind their collection.

User fees for generic new drugs for use in animals

H.R. 6433 would establish a new user fee program to help defray FDA's costs of expediting and improving the regulatory review

process for generic new drugs for use in animals. It would require FDA to assess and collect application and other user fees from manufacturers of generic new drugs for use in animals to expedite the development of such drugs and the review of new and supplemental abbreviated applications and investigational submissions for such products.

The bill would create three categories of user fees: (1) abbreviated application fees, (2) fees on generic new drug products for animals, and (3) fees on sponsors of generic new drugs for animals. The aggregate amounts of such fees are specified for each of fiscal years 2009 through 2013. Each year, the amounts to be collected could be adjusted further for workload estimates, when applicable. For fiscal year 2013, the bill also would authorize the assessment and collection of up to three months of operating reserves for the first three months of fiscal year 2014.

Fees authorized by H.R. 6433 could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. In total, we estimate that aggregate collections from fees authorized by the bill would amount to $29 million over the 2009–2013 period, assuming the necessary appropriation action.

Under the bill, user fees could not be assessed in a given year unless appropriations for salaries and expenses of FDA (excluding the amount of user fees appropriated for such fiscal year) in that year satisfy a maintenance-of-effort requirement. The user fees could be assessed if the amount appropriated exceeded the amount appropriated for 2003 increased by an adjustment factor that reflects the percentage increase in the consumer price index for all urban consumers. In addition, fees could be collected and made available to defray increases in the cost of resources allocated to reviewing abbreviated applications for generic new drugs for use in animals only to the extent that the percentage increase in those costs (excluding fees) exceeds the costs for fiscal year 2003 adjusted by the adjustment factor. This estimate assumes that such conditions would be met.

Before accounting for costs associated with additional administrative activities not covered by the user fees, CBO estimates that establishing the user fee program would reduce discretionary outlays, on net, by $2 million over the 2009–2013 period, assuming appropriation action consistent with the bill. The estimated authorization levels for collections and spending offset each other exactly from 2009 through 2013; however, spending of authorized fees lags somewhat behind their collection, thereby generating net savings over the period. In addition, the amounts available for obligation and spending for fiscal year 2013 would not include special reserve funds collected in that year. That difference would result in savings of almost $2 million for fiscal year 2013, CBO estimates.

Other administrative expenses

Funding for certain administrative activities associated with the new user fee program would not be fully covered by fees. The bill would require that FDA report annually to the Congress on its performance under the user fee program and on the fiscal status of the program. H.R. 6433 would require that FDA consult with the Congressional committees of jurisdiction and outside experts, including

industry and consumer groups, and publish its recommendations concerning reauthorization of the user fee program on a specified schedule. CBO estimates that the administrative activities associated with implementing the user fee program that are not covered by the user fees would cost less than $500,000 annually.

Estimated impact on state, local, and tribal governments: H.R. 6433 contains no intergovernmental mandates as defined in UMRA.

Estimated impact on the private sector: H.R. 6433 would establish a user fee program at FDA for sponsors of generic drugs intended for use in animals. The imposition of application, product, and sponsor fees that private entities would pay to FDA would be considered a private-sector mandate as defined in UMRA. CBO estimates that the fees collected over the 2009–2013 period would total $29 million. Those amounts would not exceed the annual threshold specified in UMRA ($136 million in 2008, adjusted annually for inflation) in any of the five years that the mandates would be effective.

Estimate prepared by: Federal Costs: Julia Christensen; Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum; Impact on the Private Sector: Paul Jacobs.

Estimate approved by: Keith J. Fontenot; Deputy Assistant Director for Health and Human Resources, Budget Analysis Division.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates regarding H.R. 6433 prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act would be created by H.R. 6433.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for H.R. 6433 is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian Tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that H.R. 6433 does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act of 1995.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

This section establishes the short title of the legislation as the "Animal Generic Drug User Fee Act of 2008".

Section 2. Findings

This section presents findings of Congress that making additional funds available through user fees for the review of abbreviated applications for generic new animal drugs would serve animal and public health by facilitating prompt review of safe and effective animal drugs.

These congressional findings also state that user fees authorized under the legislation will be used to expedite the process for generic drug development and for reviewing abbreviated applications for generic new animal drugs.

Section 3. Fees relating to abbreviated applications for generic new animal drugs

This section would amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to add authority for the FDA to collect user fees for abbreviated applications, including: applicable definitions for the various types of abbreviated applications and submissions, as well as other terms to be used in the user-fee program; provision for abbreviated application, product, and sponsor fees; the total fee revenues to be collected for each fee type for fiscal years 2009 through 2013 with adjustments (used as the basis for determining fee amounts); provision for fee waivers or reductions and collection of unpaid fees; the annual user-fee trigger requires, exclusive of user-fee appropriations, that FDA salaries and expenses appropriations for such fiscal year equal or exceed such appropriations for fiscal year 2003 multiplied by the applicable adjustment factor; provisions governing the crediting and availability of fees; and authorization of appropriations for fees for each of fiscal years 2009 through 2013.

Section 4. Accountability and reports

This section states that the Secretary of Health and Human Services (HHS) shall consult with the Committee on Energy and Commerce and the Committee on Health, Education, Labor, and Pensions (HELP), scientific and academic experts, veterinary professionals, representatives of patient and consumer advocacy groups, and the regulated industry in developing recommendations to present to Congress regarding goals for abbreviated applications for generic new animal drugs after fiscal year 2013 and for reauthorizing the user fee program.

This section requires the Secretary of HHS to submit a performance report and fiscal report to the Committee on Energy and Commerce and the Committee on HELP each fiscal year. The performance report will discuss the progress of FDA in achieving the goals of the user-fee program as identified in a letter from the Secretary of HHS to Congress. The fiscal report will also discuss the implementation of the authority to collect user fees and FDA's use of such fees during that year. These reports shall be made publicly available through FDA's Web site.

The Secretary is further directed to develop the reauthorization proposal for AGDUFA in consultation with its stakeholders, including representatives from consumer advocacy and patient groups, veterinary professionals, and the regulated industry.

Section 5. Sunset

This section states that authority for user fees will expire October 1, 2013, and that the reporting provisions will expire 120 days after that date.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER VII—GENERAL AUTHORITY

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SUBCHAPTER C—FEES

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PART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS

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 (b) for such an application.

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

(C) EXCEPTION 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).

(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.—Each person—

(A) 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

(B) 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 (b). 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 payable on or before January 31 of each year. 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 fee established under subsection (b). The fee shall be paid on or before January 31 of each year.

(B) 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)(3) 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)(3) 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)(3) for an applicant with 1 or fewer approved abbreviated applications.

(b) FEE AMOUNTS.—Except as provided in subsection (a)(1) and 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 $1,449,000 for fiscal year 2009, $1,532,000 for fiscal year 2010, $1,619,000 for fiscal year 2011, $1,712,000 for fiscal year 2012, and $1,809,000 for fiscal year 2013.

(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 $1,691,000 for fiscal year 2009, $1,787,000 for fiscal year 2010, $1,889,000 for fiscal year 2011, $1,997,000 for fiscal year 2012, and $2,111,000 for fiscal year 2013.

(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 $1,691,000 for fiscal year 2009, $1,787,000 for fiscal year 2010, $1,889,000 for fiscal year 2011, $1,997,000 for fiscal year 2012, and $2,111,000 for fiscal year 2013.

(c) ADJUSTMENTS.—

(1) WORKLOAD ADJUSTMENT.—The fee revenues shall be adjusted each fiscal year after fiscal year 2009 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).

(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2013, the Secretary may further increase the fees 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 2014. 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 2013.

(3) 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.

(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.—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) shall be retained 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 only be collected and 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).

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

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

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

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

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

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

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 2009 through 2011 and the amount of fees estimated to be collected under this section for fiscal year 2012 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2009 through 2012, 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 2013.

(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 for a 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 incurred 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 2009, not later than 60 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 2(3) of the Animal Generic Drug User Fee Act of 2008 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 2009, 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 2013, 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.

(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, 2013, 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.

SUBCHAPTER D—INFORMATION AND EDUCATION

SEC. [741.] *745.* INFORMATION SYSTEM.

The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.

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SEC. [742.] *746.* EDUCATION.

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SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

SEC. [746.] *749.* ENVIRONMENTAL IMPACT.

Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

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