

ANIMAL DRUG USER FEE AMENDMENTS 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. 6432]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 6432) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

| | Page |
|---|------|
| Amendment | 1 |
| Purpose and Summary | 5 |
| Background and Need for Legislation | 6 |
| Hearings | 6 |
| Committee Consideration | 6 |
| Committee Votes | 7 |
| Committee Oversight Findings | 7 |
| Statement of General Performance Goals and Objectives | 7 |
| New Budget Authority, Entitlement Authority, and Tax Expenditures | 7 |
| Earmarks and Tax and Tariff Benefits | 7 |
| Committee Cost Estimate | 7 |
| Congressional Budget Office Estimate | 7 |
| Federal Mandates Statement | 11 |
| Advisory Committee Statement | 11 |
| Constitutional Authority Statement | 11 |
| Applicability to Legislative Branch | 11 |
| Section-by-Section Analysis of the Legislation | 11 |
| Changes in Existing Law Made by the Bill, as Reported | 16 |

AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; REFERENCES; FINDING.

(a) **SHORT TITLE.**—This Act may be cited as the “Animal Drug User Fee Amendments 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.).

(c) **FINDING.**—Congress finds that the fees authorized by the amendments made in this Act will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, 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. 2. DEFINITIONS.

Section 739 (21 U.S.C. 379j–11) is amended—

(1) in paragraph (6), by striking “, except for an approved application for which all subject products have been removed from listing under section 510” and inserting “that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary”;

(2) in paragraph (8)(H), by striking “but not such activities after an animal drug has been approved” and inserting “but not after such application has been approved”;

(3) in paragraph (10), by striking “year being 2003” and inserting “month being October 2002”;

(4) by redesignating paragraph (11) as paragraph (12); and

(5) by inserting after paragraph (10) the following:

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

SEC. 3. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

(a) **TYPES OF FEES.**—Section 740(a) (21 U.S.C. 379j–12(a)) is amended—

(1) in paragraph (1)(A)(i), by inserting after “for an animal drug application” the following: “, except an animal drug application subject to the criteria set forth in section 512(d)(4)”;

(2) by amending paragraph (1)(A)(ii) to read as follows:

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

“(I) a supplemental animal drug application for which safety or effectiveness data are required; and

“(II) an animal drug application subject to the criteria set forth in section 512(d)(4).”.

(b) **FEE AMOUNTS.**—

(1) **TOTAL FEE REVENUES FOR APPLICATION AND SUPPLEMENT FEES.**—Section 740(b)(1) (21 U.S.C. 379j–12(b)(1)) is amended—

(A) by striking “and supplemental animal drug application fees” and inserting “and supplemental and other animal drug application fees”; and

(B) by striking “\$1,250,000” and all that follows through the period at the end and inserting “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.”.

(2) **TOTAL FEE REVENUES FOR PRODUCT FEES.**—Section 740(b)(2) (21 U.S.C. 379j–12(b)(2)) is amended by striking “\$1,250,000” and all that follows through the period at the end and inserting “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.”.

(3) **TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.**—Section 740(b)(3) (21 U.S.C. 379j–12(b)(3)) is amended by striking “\$1,250,000” and all that follows through the period at the end and inserting “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.”.

(4) **TOTAL FEE REVENUES FOR SPONSOR FEES.**—Section 740(b)(4) (21 U.S.C. 379j–12(b)(4)) is amended by striking “\$1,250,000” and all that follows through the period at the end and inserting “\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.”.

- (c) **ADJUSTMENTS TO FEES.**—Section 740(c) (21 U.S.C. 379j–12(c)) is amended—
- (1) by striking paragraph (1);
 - (2) by redesignating paragraphs (2) through (5) as paragraphs (1) through (4), respectively;
 - (3) in paragraph (1), as so redesignated—
 - (A) in the matter preceding subparagraph (A), by striking “After the fee revenues are adjusted for inflation in accordance with paragraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004” and inserting “The fee revenues shall be adjusted each fiscal year after fiscal year 2009”; and
 - (B) in subparagraph (B), by striking “, as adjusted for inflation under paragraph (1)”; and
 - (4) in paragraph (2), as so redesignated—
 - (A) by striking “2008” each place it appears and inserting “2013”; and
 - (B) by striking “2009” and inserting “2014”.
- (d) **AUTHORIZATION OF APPROPRIATIONS.**—Subparagraphs (A) through (E) of section 740(g)(3) (21 U.S.C. 379j–12(g)(3)) are amended to read as follows:
- “(A) \$15,260,000 for fiscal year 2009;
 - “(B) \$17,280,000 for fiscal year 2010;
 - “(C) \$19,448,000 for fiscal year 2011;
 - “(D) \$21,768,000 for fiscal year 2012; and
 - “(E) \$24,244,000 for fiscal year 2013.”
- (e) **OFFSET.**—Section 740(g)(4) (21 U.S.C. 379j–12(g)(4)) is amended to read as follows:
- “(4) **OFFSET.**—If the sum of the cumulative amount of fees collected under this section for 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.”.

SEC. 4. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 4 of subchapter C of chapter VII (21 U.S.C. 379j–11 et seq.) is amended by inserting after section 740 the following:

“SEC. 740A. REAUTHORIZATION; REPORTING REQUIREMENTS.

“(a) **PERFORMANCE REPORT.**—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 Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 1(c) of the Animal Drug User Fee Amendments of 2008 toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

“(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 the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate 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 the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of animal drug applications 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 the 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 the 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. ANTIMICROBIAL ANIMAL DRUG DISTRIBUTION REPORTS.

(a) REPORTS.—Section 512(l) (21 U.S.C. 360b(l)) is amended by adding at the end the following:

“(3)(A) In the case of each new animal drug described in paragraph (1) that contains an antimicrobial active ingredient, the sponsor of the drug shall submit an annual report to the Secretary on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product.

“(B) Each report under this paragraph shall specify the amount of each antimicrobial active ingredient—

“(i) by container size, strength, and dosage form;

“(ii) by quantities distributed domestically and quantities exported; and

“(iii) by dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.

“(C) Each report under this paragraph shall—

“(i) be submitted not later than March 31 each year;

“(ii) cover the period of the preceding calendar year; and

“(iii) include separate information for each month of such calendar year.

“(D) The Secretary may share information reported under this paragraph with the Antimicrobial Resistance Task Force established under section 319E of the Public Health Service Act.

“(E) The Secretary shall make summaries of the information reported under this paragraph publicly available, except that—

“(i) the summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; and

“(ii) the data shall be reported in a manner consistent with protecting both national security and confidential business information.”

(b) **FIRST REPORT.**—For each new animal drug that is subject to the reporting requirement under section 512(l)(3) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and for which an approval of an application filed pursuant to section 512(b) or 571 of such Act is in effect on the date of the enactment of this Act, the Secretary of Health and Human Services shall require the sponsor of the drug to submit the first report under such section 512(l)(3) for the drug not later than March 31, 2010.

(c) **SEPARATE REPORT.**—The reports required under section 512(l)(3) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be separate from periodic drug experience reports that are required under section 514.80(b)(4) of title 21, Code of Federal Regulations (as in effect on the date of the enactment of this Act).

SEC. 6. DESTRUCTION OF COUNTERFEIT ANIMAL DRUGS OFFERED FOR IMPORT.

Section 801(a) (21 U.S.C. 381(a)) is amended—

(1) in the third sentence, by inserting “or (4) such article is a counterfeit drug intended for use for animals other than man,” before “then such article shall be refused admission”; and

(2) by striking “Clause (2) of the third sentence of this paragraph” and inserting “Notwithstanding the preceding sentence, the Secretary of the Treasury shall cause the destruction of any such article refused admission if (1) the article is a drug intended for use for animals other than man, the article appears to be adulterated, misbranded, or in violation of section 505, and the article has a value less than \$2,000 or such amount as the Secretary of Health and Human Services may determine by regulation; or (2) the article appears to be a counterfeit drug intended for use for animals other than man. Clause (2) of the third sentence of this subsection”.

SEC. 7. SAVINGS CLAUSE.

Notwithstanding section 5 of the Animal Drug User Fee Act of 2003 (21 U.S.C. 379j–11 note), and notwithstanding the amendments made by this Act, part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in effect on the day before the date of the enactment of this Act, shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such day) that on or after September 1, 2003, but before October 1, 2008, 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 2009.

SEC. 8. EFFECTIVE DATE.

The amendments made by sections 2, 3, and 4 shall take effect on October 1, 2008, and fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall be assessed for all animal drug applications and supplemental animal drug applications received on or after such date, regardless of the date of the enactment of this Act.

SEC. 9. SUNSET DATES.

(a) **AUTHORIZATION.**—The amendments made by sections 2 and 3 cease to be effective October 1, 2013.

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

PURPOSE AND SUMMARY

H.R. 6432, the Animal Drug User Fee Amendments of 2008, amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to revise and extend the animal drug user fee program, and for other purposes.

BACKGROUND AND NEED FOR LEGISLATION

The Animal Drug User Fee Act of 2003 (ADUFA) established the animal drug user fee program. The program provides an additional revenue source for the Food and Drug Administration (FDA) to supplement appropriations from Congress for the purpose of expediting the review of animal drug applications. Before ADUFA was enacted, there were reports from FDA detailing inadequate resources for review, growing workloads, and low quality applications submitted by the industry. These problems combined were responsible for slowing down the animal drug approval process to an unacceptable rate.

In response to these problems, ADUFA was enacted. The program requires that manufacturers of new animal drugs pay application fees for each new product, annual manufacturing establishment fees, annual product fees, and sponsor fees in an effort to expedite the animal drug review process. FDA sets performance goals, mutually agreed upon by FDA and the regulated industry. The fees are used to meet the performance goals. The Secretary of Health and Human Services (HHS) is required to send a letter identifying these goals to the Chairman of the House Committee on Energy and Commerce and the Chairman of the Senate Committee on Health, Education, Labor, and Pensions (HELP), and this letter is included in the Congressional Record. Fees currently represent about 13 percent of the agency's budget for animal drug review and for 60 full-time equivalent employees.

There is general agreement that ADUFA has been successful in eliminating the review backlog and has improved the timeliness and predictability of reviews. ADUFA expires on October 1, 2008, prompting congressional action for its reauthorization.

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. 6432 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. 6432 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. 6432 reported to the House. A motion by Mr. Dingell to order H.R. 6432 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. 6432 are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 6432 is to reauthorize the animal drug user fee program, which provides resources for expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational 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. 6432 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. 6432 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. 6432 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. 6432 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. 6432, the Animal Drug User Fee Amendments 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. 6432—Animal Drug User Fee Amendments of 2008

Summary: H.R. 6432 would authorize the collection and spending of user fees by the Food and Drug Administration (FDA) for certain activities to expedite the development and marketing approval of drugs for use in animals. Fees would supplement appropriated funds to cover FDA's cost associated with reviewing certain applications and investigational submissions for animal drugs. Such fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. The legislation would extend through fiscal year 2013 and make several technical changes to the existing user fee program for animal drugs, which expires at the end of fiscal year 2008.

H.R. 6432 would also require sponsors of new animal drugs to submit annual reports to FDA on certain products that contain antimicrobial active ingredients, and it would require FDA to make summaries of such information publicly available.

CBO estimates that implementing H.R. 6432 would reduce discretionary outlays, on net, by \$6 million over the 2009–2013 period, assuming the necessary authorities are provided in appropriation acts. The bill would not affect direct spending or revenues.

H.R. 6432 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

The bill would impose private-sector mandates, as defined in UMRA, because it would require manufacturers of drugs for use in animals to pay specified fees to FDA and to submit reports to the agency for certain products. CBO estimates that the direct cost of complying with these requirements would not exceed the annual threshold 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. 6432 is shown in the following table. The costs of this legislation fall primarily 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 | -15 | -17 | -19 | -22 | -27 | -101 |
| Estimated Outlays | -15 | -17 | -19 | -22 | -27 | -101 |
| Spending of User Fees: | | | | | | |
| Estimated Authorization Level | 15 | 17 | 19 | 22 | 27 | 101 |
| Estimated Outlays | 11 | 17 | 19 | 22 | 24 | 93 |
| Administrative Expenses: | | | | | | |
| Estimated Authorization Level | 1 | * | * | * | * | 2 |
| Estimated Outlays | 1 | * | * | * | * | 2 |
| Net Effect on Spending by FDA: | | | | | | |
| Estimated Authorization Level | 1 | * | * | * | * | 2 |
| Estimated Outlays | -3 | * | * | * | -3 | -6 |

Note: * = between -\$500,000 and \$500,000. Components may not sum to totals because of rounding.

Basis of estimate: For this estimate, CBO assumes that H.R. 6432 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 the program. Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 6432 would reduce discretionary outlays, on net, by \$6 million over the 2009–2013 period, primarily because the spending of authorized fees lags slightly behind their collection.

User fees for animal drugs

H.R. 6432 would authorize FDA to assess and collect certain fees from manufacturers of drugs for use in animals to help defray FDA's costs of expediting the regulatory review process for such drugs. Under current law, the user fee program for animal drugs will expire at the end of fiscal year 2008.

Similar to the existing fee structure, four categories of user fees would be authorized by the bill: (1) animal drug application and supplement fees, (2) animal drug product fees, (3) animal drug establishment fees, and (4) animal drug sponsor fees. The bill would authorize the appropriation of specific aggregate amounts of collections for each fiscal year 2009 through 2013. Collections could be modified each year based on certain workload estimates, when applicable. The legislation also would make several technical changes to the existing user fee program.

Fees authorized by H.R. 6432 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 FDA would assess and collect the amounts specified in the bill without any additional adjustment for workload. (No such adjustments have occurred over the last 5 years of the existing program and we expect that they would not occur in the future.) For fiscal year 2013, the bill would authorize the assessment and collection of up to three months of operating reserves for the first three months of fiscal year 2014. In total, we estimate aggregate collections from fees authorized by the bill would amount to \$101 million over the 2009–2013 period.

The legislation would retain the existing statutory limitation that user fees cannot be assessed in a given year unless appropria-

tions 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 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 animal drug applications 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 and other activities required by the bill, CBO estimates that authorizing the user fee program for the 2009–2013 period would reduce discretionary outlays, on net, by \$8 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 savings over the period. In addition, amounts available for obligation and spending for fiscal year 2013 would not include additional special reserve funds collected in that year. CBO estimates that difference would result in savings of \$3 million for fiscal year 2013.

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. 6432 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. In addition, H.R. 6432 would also require sponsors of animal drugs to submit annual reports to FDA on certain new products that contain antimicrobial active ingredients, and it would require FDA to make summaries of such information publicly available. CBO estimates that the administrative activities associated with implementing the user fee program that are not covered by the user fees and other activities required by the bill would cost between \$1 million and \$2 million over the 2009–2013 period.

Estimated impact on state, local, and tribal governments: H.R. 6432 contains no intergovernmental mandates as defined in UMRA.

Estimated impact on the private sector: H.R. 6432 would require sponsors of drugs intended for use in animals to pay application, product, establishment, and other related fees to FDA. The bill also would require sponsors of new animal drugs containing active antimicrobial ingredients to submit an annual report to FDA regarding the amount of these ingredients and additional information specified by the bill.

Both of these requirements would be considered private-sector mandates as defined in UMRA. CBO estimates that the fees collected over the 2009–2013 period would total \$101 million. CBO also estimates that the direct cost of complying with both of these requirements 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. 6432 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. 6432.

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. 6432 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. 6432 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; references; finding

Section 1 designates the short title of the bill as the “Animal Drug User Fee Amendments of 2008”; states that 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.); and states that the fees authorized by this Act will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions.

Section 2. Definitions

Section 2 amends three definitions found in section 739 of the Federal Food, Drug, and Cosmetic Act (FFDCA). This section modifies the definition of the term “animal drug sponsor” to mean either an applicant named in an animal drug application 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 animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary. This section also modifies the definition of the term “adjustment factor” so that the base or comparator month is October 2002. Finally, this section modifies the definition of the term “process for the review of animal drug applications” to clarify that FDA is allowed to use animal drug user fees to review advertising and labeling for purposes of a supplemental abbreviated application.

Additionally, section 2 includes a new term for “person.” The term “person” is defined to include an affiliate thereof.

Section 3. Authority to assess and use animal drug fees

Section 3 amends section 740(a) of the FFDCA. This section states that each person that submits an animal drug application shall be subject to application and supplement fees, product fees, establishment fees, and sponsor fees unless the animal drug application is subject to the criteria set forth in section 512(d)(4). Additionally, this section clarifies that each person that submits a supplemental animal drug application, for which safety or effectiveness data are required, or an animal drug application, subject to the criteria set forth in section 512(d)(4), shall be subject to application and supplement fees, product fees, establishment fees, and sponsor fees. This fee amount shall equal 50 percent of the amount of the fee for animal drug applications not subject to section 512(d)(4).

Section 3 amends section 740(b) of the FFDCA. This section increases total fee revenues for application and supplement fees, product fees, establishment fees, and sponsor fees.

Section 3 amends section 740(c) of the FFDCA. This section requires that fee revenues shall be adjusted each fiscal year (FY) after FY 2009. In addition, this section modifies the existing final year adjustment provision. For FY 2013, the Secretary may further increase the fees to provide for up to three months of operating reserves of carryover user fees for the review of animal drug applications for the first three months of FY 2014. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for FY 2013. This one-time increase in fees in FY 2013, if necessary, assures that the agency will have up to three months of operating reserves on hand at the end of FY 2013, when this legislation will sunset.

Section 3 amends section 740(g)(3) of the FFDCA. This section authorizes to be appropriated for fees under this section: \$15,260,000 for FY 2009; \$17,280,000 for FY 2010; \$19,448,000 for FY 2011; \$21,768,000 for FY 2012; and \$24,244,000 for FY 2013.

Section 3 amends section 740(g)(4) of the FFDCA. This section clarifies that if the sum of the cumulative amount of fees collected under this section for fiscal years 2009 through 2011 and the amount of fees estimated to be collected under this section for FY 2012 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2009 through 2012, the excess amount shall be credited to FDA’s appropriation account. It shall then be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to Appropriation Acts for FY 2013.

Section 4. Reauthorization; reporting requirements

New section 740A requires that, beginning with FY 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 a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on HELP of the Senate. This report shall discuss the progress of FDA in achieving the goals of the Animal Drug User Fee Amendments of 2008, as identified in a letter from the Secretary of HHS to Congress. These goals include expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during each fiscal year; the future plans of FDA for meeting the goals; the review times for abbreviated new animal drug applications; and the administrative procedures adopted by FDA to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

New section 740A also requires that, beginning with FY 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 a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on HELP of the Senate. The report must include information about (1) whether each of the three funding triggers has been met for each fiscal year; (2) total costs for the process of review of animal drug applications, as defined in ADUFA I; and (3) the amounts paid from user fee revenues and appropriations.

New section 740A requires that the Secretary make these reports available to the public on FDA's Web site.

In addition, new section 740A requires that, in developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the review of animal drug applications for the first five fiscal years after FY 2013, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with the following: the Committee on Energy and Commerce of the House of Representatives; the Committee on HELP of the Senate; scientific and academic experts; veterinary professionals; representatives of patient and consumer advocacy groups; and the regulated industry.

New section 740A states that, prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall publish a notice in the Federal Register requesting public input on the reauthorization; hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals; provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and publish the comments on FDA's Web site.

New section 740A requires that, not less frequently than once every four months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to solicit their views on the reauthorization and their suggestions for changes to this part. This language is based on the latest Prescription Drug User Fee Act (PDUFA) reauthorization, which became Public Law 110-

85 on September 27, 2007, and which requires monthly meetings between FDA and patient and consumer groups during negotiations with the regulated industry. This Act requires less frequent meeting because, to date, fewer patient and consumer groups have attended the ADUFA meetings than have attended the PDUFA meetings. If, however, it becomes apparent that more veterinary, patient, and consumer groups are interested in participating in these discussions with FDA, it may be appropriate for FDA to increase the frequency of these discussions.

New section 740A requires that, after negotiation with the regulated industry, the Secretary shall present the recommendations to the Committee on Energy and Commerce of the House of Representatives and the Committee on HELP of the Senate; publish such recommendations in the Federal Register; provide for a period of 30 days for the public to provide written comments on such recommendations; hold a meeting at which the public may present its views on such recommendations; and after consideration of such public views and comments, revise such recommendations as necessary. Not later than January 15, 2013, the Secretary shall then transmit to Congress the revised recommendations, a summary of the views and comments received, and any changes made to the recommendations in response to such views and comments.

New section 740A states that, prior to presenting recommendations to Congress, the Secretary shall make publicly available on FDA's Web site minutes of all negotiation meetings conducted under this subsection between FDA and the regulated industry. The minutes 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.

Section 5. Antimicrobial animal drug distribution reports

Section 5 amends section 512(l) of the FFDCFA. This section requires that for each new animal drug containing an antimicrobial active ingredient, for which an approval of an application filed pursuant to subsection (b) or section 571 is in effect, the sponsor of the drug shall submit an annual report to the Secretary on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. In analyzing this information, FDA should take steps to avoid duplication of data that may result from receiving both manufacturer-labeled and distributor-labeled information for a single antimicrobial active ingredient.

The Committee expects FDA to use information garnered from these annual reports in its continuing analysis of the interactions (including drug resistance), efficacy, and safety of antibiotics approved for use in both humans and food-producing animals.

Each report shall specify the amount of each antimicrobial active ingredient by container size, strength, and dosage form; by quantities distributed domestically and quantities exported; and by dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product. Each report shall be submitted not later than March 31 of each year, shall cover the period of the preceding calendar year, and shall include separate information for each month of such calendar year. There is precedent for

monthly reporting as evidenced by the monthly data collection on antibiotic resistance that is gathered under the National Antimicrobial Resistance Monitoring System (NARMS) operated cooperatively by the Food and Drug Administration's Center for Veterinary Medicine, U.S. Department of Agriculture, and the Centers for Disease Control and Prevention.

The Secretary may share information reported under this section with the Antimicrobial Resistance Task Force established under section 319E of the Public Health Service Act. As of the date of enactment of this Act, the Antimicrobial Resistance Task Force was composed solely of representatives from Federal agencies, as determined by the Secretary of Health and Human Services. It is the intention of this Committee that information reported under this section be available only to representatives of Federal agencies. If the membership of the Antimicrobial Resistance Task Force is ever expanded to include representatives of non-Federal agencies, the appropriate steps should be taken to ensure that representatives of non-Federal agencies only receive information consistent with what is provided publicly under this section.

The Secretary shall make summaries of the information reported in this section publicly available. Summary data shall be reported by antimicrobial class, and no class with fewer than three distinct sponsors of approved applications shall be independently reported. Data shall be reported in a manner consistent with protecting both national security and confidential business information.

This section requires that for each new animal drug that is subject to this new reporting requirement, and for which an approval of an application filed pursuant to section 512(b) or 571 of such Act is in effect on the date of the enactment of this Act, the Secretary of HHS shall require the sponsor of the drug to submit the first report for the drug no later than March 31, 2010.

This section clarifies that the new reports required by this section are separate from periodic drug experience reports that are required under section 514.80(b)(4) of title 21, Code of Federal Regulations (as in effect on the date of the enactment of this Act).

Section 6. Destruction of counterfeit animal drugs offered for import

Section 6 amends section 801(a) of the FDCA. This section states that the Secretary of the Treasury may refuse to allow the admission of a drug intended for use in animals into the United States, if it is deemed to be a counterfeit. In addition, this section requires the Secretary of Treasury to cause the destruction of any animal drug refused for admission if the drug (1) appears to be adulterated, misbranded, or in violation of section 505 and the article has a value less than \$2,000, or such amount as the Secretary of HHS may determine by regulation; or (2) the drug appears to be a counterfeit animal drug.

Section 7. Savings clause

Section 7 states that, notwithstanding section 5 of the Animal Drug User Fee Act of 2003 and notwithstanding the amendments made by this Act, part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, shall continue to be in effect with respect to animal drug applications and supplemental animal

drug applications that on or after September 1, 2003, but before October 1, 2008, were accepted by FDA for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to FY 2009.

Section 8. Effective date

Section 8 states that the amendments made by sections 2, 3, and 4 shall take effect on October 1, 2008, and the fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall be assessed for all animal drug applications received on or after such date, regardless of the date of the enactment of this Act.

Section 9. Sunset dates

Section 9 states that the amendments made by sections 2 and 3 cease to be effective on October 1, 2013. Section 8 further states that section 4 ceases to be effective on January 31, 2014.

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

* * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * *

NEW ANIMAL DRUGS

SEC. 512. (a) * * *

* * * * *

(1)(1) * * *

* * * * *

(3)(A) *In the case of each new animal drug described in paragraph (1) that contains an antimicrobial active ingredient, the sponsor of the drug shall submit an annual report to the Secretary on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product.*

(B) *Each report under this paragraph shall specify the amount of each antimicrobial active ingredient—*

(i) by container size, strength, and dosage form;

(ii) by quantities distributed domestically and quantities exported; and

(iii) by dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.

(C) *Each report under this paragraph shall—*

- (i) be submitted not later than March 31 each year;
- (ii) cover the period of the preceding calendar year; and
- (iii) include separate information for each month of such calendar year.

(D) The Secretary may share information reported under this paragraph with the Antimicrobial Resistance Task Force established under section 319E of the Public Health Service Act.

(E) The Secretary shall make summaries of the information reported under this paragraph publicly available, except that—

(i) the summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; and

(ii) the data shall be reported in a manner consistent with protecting both national security and confidential business information.

* * * * *

CHAPTER VII—GENERAL AUTHORITY

* * * * *

SUBCHAPTER C—FEES

* * * * *

PART 4—FEES RELATING TO ANIMAL DRUGS

SEC. 739. DEFINITIONS.

For purposes of this part:

(1) * * *

* * * * *

(6) The term “animal drug sponsor” means either an applicant named in an animal drug application [, except for an approved application for which all subject products have been removed from listing under section 510] 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 animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

* * * * *

(8) The term “process for the review of animal drug applications” means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

(A) * * *

* * * * *

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

* * * * *

(10) The term “adjustment factor” applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator **[year being 2003]** *month being October 2002*.

(11) *The term “person” includes an affiliate thereof.*

[(11)] (12) The term “affiliate” refers to the definition set forth in section 735(11).

SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

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

(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

(A) IN GENERAL.—Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

(i) A fee established in subsection (b) for an animal drug application, *except an animal drug application subject to the criteria set forth in section 512(d)(4)*; and

[(i)] A fee established in subsection (b) for a supplemental animal drug application for which safety or effectiveness data are required, in an amount that is equal to 50 percent of the amount of the fee under clause (i). **]**

(ii) A fee established in subsection (b), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

(I) a supplemental animal drug application for which safety or effectiveness data are required; and

(II) an animal drug application subject to the criteria set forth in section 512(d)(4).

* * * * *

(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 AND SUPPLEMENT FEES.—The total fee revenues to be collected in animal drug application fees under subsection (a)(1)(A)(i) **[and supplemental animal drug application fees]** *and supplemental and other animal drug application fees* under subsection (a)(1)(A)(ii) shall be **[\$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal year 2005, and \$2,500,000 in fiscal years 2006, 2007, and 2008.]** *\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.*

(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(2) shall be **[\$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal year 2005, and \$2,500,000 in fiscal years 2006, 2007, and 2008.]** *\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.*

(3) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(3) shall be **[\$1,250,000 in fiscal year 2004,**

\$2,000,000 in fiscal year 2005, and \$2,500,000 in fiscal years 2006, 2007, and 2008.] *\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.*

(4) TOTAL FEE REVENUES FOR SPONSOR FEES.—The total fee revenues to be collected in sponsor fees under subsection (a)(4) shall be **[\$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal year 2005, and \$2,500,000 in fiscal years 2006, 2007, and 2008.]** *\$3,815,000 for fiscal year 2009, \$4,320,000 for fiscal year 2010, \$4,862,000 for fiscal year 2011, \$5,442,000 for fiscal year 2012, and \$6,061,000 for fiscal year 2013.*

(c) ADJUSTMENTS.—

[(1) INFLATION ADJUSTMENT.—The revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

[(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year for which fees are being established; or

[(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2004 under this subsection.]

[(2) (1) WORKLOAD ADJUSTMENT.—[After the fee revenues are adjusted for inflation in accordance with paragraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004] *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) * * *

(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)[, as adjusted for inflation under paragraph (1)].

[(3) (2) FINAL YEAR ADJUSTMENT.—For fiscal year **[2008] 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 animal drug applications for the first 3 months of fiscal year **[2009] 2014**. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will 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 **[2008] 2013**.

[(4)] (3) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

[(5)] (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 animal drug applications.

* * * * *

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) * * *

* * * * *

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

- [(A)] \$5,000,000 for fiscal year 2004;
- [(B)] \$8,000,000 for fiscal year 2005;
- [(C)] \$10,000,000 for fiscal year 2006;
- [(D)] \$10,000,000 for fiscal year 2007; and
- [(E)] \$10,000,000 for fiscal year 2008;]
- (A) \$15,260,000 for fiscal year 2009;
- (B) \$17,280,000 for fiscal year 2010;
- (C) \$19,448,000 for fiscal year 2011;
- (D) \$21,768,000 for fiscal year 2012; and
- (E) \$24,244,000 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 animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees.

[(4)] OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriations Acts for such fiscal year 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 a subsequent fiscal year.】

(4) OFFSET.—*If the sum of the cumulative amount of fees collected under this section for 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.*

* * * * *

SEC. 740A. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) *PERFORMANCE REPORT.*—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 Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 1(c) of the Animal Drug User Fee Amendments of 2008 toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

(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 the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate 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 the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of animal drug applications 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 the 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 the 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.

* * * * *

CHAPTER VIII—IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof

to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs or devices manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs or devices be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll), or (4) *such article is a counterfeit drug intended for use for animals other than man*, then such article shall be refused admission, except as provided in subsection (b) of this section. If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 760 or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. **[Clause (2) of the third sentence of this paragraph]** *Notwithstanding the preceding sentence, the Secretary of the Treasury shall cause the destruction of any such article refused admission if (1) the article is a drug intended for use for animals other than man, the article appears to be adulterated, misbranded, or in violation of section 505, and the article has a value less than \$2,000 or such amount as the Secretary of Health and Human Services may determine by regulation; or (2) the article appears to be a counterfeit drug intended for use for animals other than man. Clause (2) of the third sentence of this subsection shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.*

* * * * *