

wasting that occurs in ALS, and it is characterized by progressive muscle weakness in the voluntary muscles. PLS belongs to a group of disorders known as motor neuron diseases that develop when the nerve cells that control voluntary muscle movement degenerate and die. This usually occurs after the age of 50, and causes a gradual weakness in the muscles.

Symptoms for the individuals afflicted by the disease may include difficulty with balance, weakness and stiffness in the legs, and clumsiness. Other symptoms may include sudden and involuntary muscle spasms in the hands, feet, or legs, and maybe speech problems due to the involvement of the facial muscles. The disease, which scientists believe is not hereditary, progresses gradually over a number of years or even decades.

The efforts of the Spastic Paraplegia Foundation have been paramount in raising funds dedicated to finding cures and providing information about PLS. Thanks to the dedication and hard work of many individuals at the Spastic Paraplegic Foundation, in just 5 years, more than \$1 million has been targeted to research on SPF conditions and thousands of people have been helped.

I would like to thank the National Institute of Neurological Disorders and Stroke at the National Institute of Health for conducting a broad range of research on neuromuscular disorders such as PLS. Their research has been aimed at developing techniques to diagnose, treat, prevent, and ultimately cure these devastating diseases.

In closing, I would like to thank again the author of this resolution, Mr. JOE BACA, my friend from California, for raising public awareness about PLS. I encourage all of my colleagues to vote in favor of this resolution.

I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I am pleased to yield 5 minutes to the gentleman from California (Mr. BACA), who is the author of this resolution.

Mr. BACA. Mr. Speaker, I rise in support of H. Res. 896, the Primary Lateral Sclerosis Awareness Month Act. I would like to thank Chairman DINGELL, Chairman PALLONE, Ranking Member NATHAN DEAL, along with Mr. TERRY, for helping guide this legislation through the committee.

Primary lateral sclerosis, commonly referred to as PLS, is a neurological disorder that affects the cells that control the voluntary muscles. PLS is similar to ALS, often called Lou Gehrig's disease.

Can you imagine someone who is diagnosed with PLS, but yet they are told that it is ALS and in fact it was PLS that they were diagnosed, and thinking that they only had X amount of time to live, its impact it has on the family members and others as they begin to look at that disease because not enough research has been done? That is devastating to the individuals and the family members who are diag-

nosed. That is why it is important that we do the research.

This illness is, of course, named after the famous Yankee baseball player who suffered and died of ALS before we knew much about it. As with many other neurological disorders, once the nerve cells that control the voluntary muscles are affected, a person's physical ability to function becomes very difficult.

Symptoms of PLS include difficulties with balance, sudden involuntary muscle spasms in the hands, feet, legs, and speech problems when the facial muscles are affected. But these symptoms are not unique to PLS alone. PLS is often very difficult to diagnose because the symptoms vary, and may progress slowly over a period of time of many years. I would rather have someone be diagnosed with the right PLS versus ALS to know that they are going to live a lot longer.

Because of this, many Americans are still unaware of the severe nature of PLS, even though the disorder was first discovered in 1850 in France. That is why we need to continue with greater and more expansive research.

My resolution serves to raise awareness across the Nation by urging all Americans to recognize February of 2009 as PLS Awareness Month. This resolution emphasizes the need of greater funding and more research to combat neuromuscular disease. With this bill, Congress is helping educate our doctors and nurses and the rest of the medical community about PLS.

However, there are many courageous and dedicated individuals who are doing this already.

One is my good friend, Hardy Brown, who is from my district and, of course, owner of the Black Voice Newspaper in California. He has dedicated his life to serve as a voice for underrepresented communities in the Inland Empire. Throughout his life, Hardy Brown has done a tremendous job in the community raising awareness of Lou Gehrig's disease. Now he is diagnosed with PLS. Hardy Brown, once a vibrant, active leader, is now in a wheelchair doing what he can despite difficulties moving, speaking, and typing.

Another individual, Tyonja Bathgate from Maryland, whose husband was diagnosed with PLS, has torn herself from her husband's bedside to advocate on behalf of this issue.

We want to thank these individuals and all others who have worked to raise the awareness of these conditions. But we must do more, and urging the establishment of a PLS Awareness Month is a step in the right direction. There is currently no cure for PLS, and hopefully one day we will find a cure. God willing, we will do that.

Treatment and symptoms vary from person to person, and the age of onset is generally between the ages of 35 to 66, and, as it was stated, over 2,000 have been diagnosed with this.

□ 1530

Because of the similar symptoms, researchers believe that PLS patients are

often diagnosed with ALS, and I have already stated the effects it has on families when they are told that.

Most of us have heard of Lou Gehrig's disease, but this legislation today will help raise the awareness and stress the importance of a very familiar disorder. The medical community must be able to properly diagnose those individuals who suffer from PLS and other neuromuscular disease to ensure proper care and treatment.

I urge my colleagues to vote for H. Res. 896, and join me and all individuals and organizations in this effort to fight this devastating illness. And I want to thank again Mr. PALLONE, Mr. TERRY for helping us with this legislation and many of the others that will support this to make sure that not many other individuals suffer from this type of disease that will affect others as well.

Mr. TERRY. We have no further speakers, so I will just once again thank Mr. BACA for writing this resolution and bringing it, Mr. PALLONE, Mr. DINGELL, Mr. BARTON for making sure that it, in such a speedy manner, got to the House floor.

I yield back.

Mr. PALLONE. Mr. Speaker, I have no further requests for time as well, and I yield back the balance of my time and urge support for the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and agree to the resolution, H. Res. 896, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the resolution, as amended, was agreed to.

The title was amended so as to read:

"A resolution recognizing the need to pursue research into the causes, a treatment, and an eventual cure for primary lateral sclerosis, supporting the goals and ideals of Primary Lateral Sclerosis Awareness Month, and for other purposes."

A motion to reconsider was laid on the table.

#### ANIMAL DRUG USER FEE AMENDMENTS OF 2008

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass 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, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6432

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

Sec. 1. Table of contents.  
Sec. 2. References in Act.

#### TITLE I—ANIMAL DRUG USER FEE AMENDMENTS

Sec. 101. Short title; finding.

Sec. 102. Definitions.  
 Sec. 103. Authority to assess and use animal drug fees.  
 Sec. 104. Reauthorization; reporting requirements.  
 Sec. 105. Antimicrobial animal drug distribution reports.  
 Sec. 106. Savings clause.  
 Sec. 107. Effective date.  
 Sec. 108. Sunset dates.

**TITLE II—ANIMAL GENERIC DRUG USER FEE**

Sec. 201. Short title; findings.  
 Sec. 202. Fees relating to abbreviated applications for generic new animal drugs.  
 Sec. 203. Accountability and reports.  
 Sec. 204. Sunset dates.

**TITLE III—TECHNICAL CORRECTIONS TO FDAAA**

Sec. 301. Consideration of certain petitions.  
 Sec. 302. Registry and results data bank.

**SEC. 2. 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.).

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

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

(a) **SHORT TITLE.**—This title may be cited as the “Animal Drug User Fee Amendments of 2008”.

(b) **FINDING.**—Congress finds that the fees authorized by the amendments made in this title 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. 102. 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. 103. 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)”;

(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. 104. 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 101(b) 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. 105. ANTIMICROBIAL ANIMAL DRUG DISTRIBUTION REPORTS.

(a) REPORTS.—Section 512(l) (21 U.S.C. 360b(1)) 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 title, 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 title).

#### SEC. 106. 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 title, 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 title, 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. 107. EFFECTIVE DATE.

The amendments made by sections 102, 103, and 104 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 title, 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 title.

#### SEC. 108. SUNSET DATES.

(a) AUTHORIZATION.—The amendments made by sections 102 and 103 cease to be effective October 1, 2013.

(b) REPORTING REQUIREMENTS.—The amendment made by section 104 ceases to be effective January 31, 2014.

### TITLE II—ANIMAL GENERIC DRUG USER FEE

#### SEC. 201. SHORT TITLE; FINDINGS.

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

(b) 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 title 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. 202. 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 re-listing under section 510 if the generic new animal drug product has been withdrawn from listing and re-listed. 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 investiga-

tional 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. 203. 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 202, 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 201(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. 204. SUNSET DATES.

(a) AUTHORIZATION.—The amendments made by section 202 shall cease to be effective October 1, 2013.

(b) REPORTING REQUIREMENTS.—The amendment made by section 203 shall cease to be effective January 31, 2014.

### TITLE III—TECHNICAL CORRECTIONS TO FDAAA

#### SEC. 301. CONSIDERATION OF CERTAIN PETITIONS.

Subparagraph (A) of section 505(q)(1) (21 U.S.C. 355(q)(1)) is amended by adding at the end the following:

“Consideration of the petition shall be separate and apart from review and approval of any application.”.

#### SEC. 302. REGISTRY AND RESULTS DATA BANK.

Paragraph (3) of section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) is amended—

(1) in the matter preceding clause (i) in subparagraph (C), by striking “the following elements” and all that follows through “520(m) of such Act:” and inserting “for each applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act, the following elements:”; and

(2) in clauses (i) and (iii) of subparagraph (I), by striking the term “drugs described in subparagraph (C)” each place such term appears and inserting “applicable clinical trials described in subparagraph (C)”.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Georgia (Mr. DEAL) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

#### GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and include extraneous material on the bill under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Prior to 2003, the FDA’s review of animal drug submissions was taking over a year and a half to be completed. This obviously led to serious concerns that new and innovative pharmaceutical products were not making their way onto the marketplace in order to treat our Nation’s pets, as well as food animals that help sustain the Nation’s food supply.

Accordingly, in 2003, Congress enacted the Animal Drug User Fee Act (ADUFA) which was modeled after the successful user fee programs for the review of human drug and medical device submissions. Like the user fee programs that preceded it, ADUFA authorized the FDA to collect fees to help ensure that the agency had the resources it needed to provide a timely review of animal drug applications.

The legislation before us today would reauthorize the ADUFA program for another 5 years. Under this legislation, the amount of fees collected for the review of animal drug submissions would increase from \$15 million to \$24 million over 5 years, for a total of \$98 million. Revenues would be derived from a mix of application, product, establishment and sponsor fees.

The legislation would also improve the uniform collection and reporting of data to FDA on the sales about animal drugs that contain an antibiotic ingredient.

During the debate on reauthorization of ADUFA, we heard many concerns about the use of antibiotics in animal populations for non-therapeutic purposes and the threat that these practices pose to human health. This bill

includes language that would enhance FDA’s current data collection by creating a new antimicrobial animal drug use data report for all food-producing animals. The report puts critical information in one place for FDA; otherwise, the agency would have to search through warehouses of multiple paper reports.

In addition to the reauthorization of ADUFA, this legislation would establish a new animal generic drug user fee. According to FDA, the average review time of an animal generic drug submission was 570 days in Fiscal Year 2007, in spite of a 180-day statutory requirement. At the end of last year there was a recorded backlog of 446 submissions waiting for review and agency action.

Accordingly, the bill before us would provide for the collection of user fees increasing annually from \$4.8 million to \$6 million over 5 years, for a total of \$27 million. And these additional revenues are designed to help speed up the review process. By Year 5 of the authorization period, most reviews of generic animal drug submissions should occur in 270 days or less, a substantial improvement over the time it is now taking FDA to conduct such reviews.

Mr. Speaker, I am also pleased that the generic drug industry and FDA have been able to work out this agreement. If enacted, AGDUFA will speed lower cost animal drugs to the marketplace and bring significant savings to ranchers, farmers and pet owners. While that is an important and noteworthy goal, I also think it is equally, if not more important, to ensure for the timely review of generic human drug applications.

There is a provision in this bill that would improve the speed in which FDA reviews generic drug applications, and that provision makes a technical correction to the Food and Drug Administration Amendments Act of 2007 as it relates to the application process for obtaining FDA approval of certain new generic drugs.

Citizen petitions can be submitted to FDA to raise issues about drugs that are being considered in the application process. At the time of negotiations on the Food and Drug Administration Amendments Act of 2007, an agreed-upon sentence was inadvertently dropped from our final version of that bill. The sentence makes clear that consideration of a citizen petition regarding a drug is to be separate and apart from review and approval of any application for the drug. The language included in the bill we are considering today restores that sentence.

There is another correction to the FDA Amendments Act that is included in the bill before us. This change concerns the types of information to be included in the clinical trials data bank established under that law. More specifically, the issue is adverse event information on drugs and on medical devices.

Adverse event information was clearly intended to be included in the data

bank for both drugs and devices. Express specific requirements to that effect were included in multiple drafts of the legislation. In negotiations, however, it was agreed that rather than the bill itself including express specific requirements regarding adverse event information, the FDA would issue regulations that would set the specific requirements. In drafting the “regulations” approach, the reference to medical devices was inadvertently dropped, and that was a simple mistake. So the bill before us today corrects that mistake.

In closing, I want to thank my Republican colleagues for working for us in a bipartisan fashion to move this bill forward. Mr. DEAL, Mr. BARTON and of course Mr. DINGELL all worked together, so this is, in fact, a bipartisan bill, and a very important bill as well.

Mr. Speaker, I reserve the balance of my time.

Mr. DEAL of Georgia. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, today the House is set to pass legislation reauthorizing the Animal Drug User Fee Act, also known as ADUFA. This legislation represents a compromise between the parties, the administration, and the industry.

Development of animal drugs can take years and cost millions of dollars. A predictable review process is important to make sure that these products are approved in a timely way. Since the passage of ADUFA in 2003, the review times for new animal drugs went from 295 days in Fiscal Year 2004 to 180 days in Fiscal Year 2008.

We need to reauthorize this program before we leave for the August recess. If we fail to do so, the FDA may have to begin issuing reduction in force notices to its employees. The bill before us today will provide financial stability for the program and improve the health information infrastructure for drug review. It will also provide more user revenue for the program.

Along with ADUFA, for the first time, Congress is set to pass legislation which would create the Animal Generic Drug User Fee Act, or AGDUFA. AGDUFA will allow the FDA to collect user fees, thereby improving the times necessary for generic drug approval. This will not only bring generics to the market more quickly, but will also lower costs for consumers. If AGDUFA is authorized, approval times could be reduced from 700 days in Fiscal Year 2009, to around 270 days in Fiscal Year 2013.

Mr. Speaker, I look forward to the passage of both of these pieces of legislation in the bill that is before us today.

I would reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I am pleased to yield 3 minutes to the gentleman from California (Mr. WAXMAN) who, I must add, has been such an outstanding spokesman on FDA issues over the years, and particularly pro-

moting generic drugs. I yield to the gentleman 3 minutes.

Mr. WAXMAN. Mr. Speaker, I thank the chairman of our subcommittee for yielding to me.

This bill that we are considering now, the Animal Drug User Fee Act, or ADUFA, will enhance and improve FDA's ability to promptly review new medicines for animals, and that is very important that we all support this.

This reauthorization has also given us an opportunity to look at providing FDA with new tools to address a related public health crisis, the problem of antibiotic resistance caused by the industrial farming practice of using human antibiotics for non-therapeutic uses in food producing animals.

We now have an overwhelming body of evidence showing that the overuse of antibiotics in industrial farm production is threatening to destroy the effectiveness of some of our most important antibiotics for human use. Many of the world's most prestigious experts, the Institute of Medicine, the Pew Commission, World Health Organization and Government Accountability Office have warned about the dangers to global public health of such widespread overuse. These drugs are breeding resistant microorganisms that can and do get transferred to humans. They also leach into the environment and show up in our drinking water. The experts have told us that the more antibiotics we consume, the more resistance develops.

The ADUFA bill we are considering includes a provision to increase the availability and accessibility of data on the amount of animal antibiotics being distributed. This data will help us to determine how resistant bugs are developing and inform research on ways to stop those bugs from threatening human health.

This is an important step forward, and I appreciate the cooperation of Chairman DINGELL and Chairman PALLONE in helping us to get this done.

But let me be clear: This is only just the beginning. We, in Congress, need to do much more to address the problem of antibiotic resistance. It is imperative that we look at ways to curtail the practice of using the same antibiotics that are so vitally important for preventing and curing human disease for non-therapeutic uses in food-producing animals.

I look forward to continuing to work with our colleagues on this important issue.

Mr. DEAL of Georgia. Mr. Speaker, I would yield at this time such time as he may consume to the gentleman from Indiana (Mr. BUYER).

Mr. BUYER. Mr. Speaker, I need to discuss an amendment that was adopted at the committee that is not in this bill today. We, as a country, are facing a tremendous challenge, and that is, with the advent of the Internet, it is very easy for people to get on the Internet; they go to a Web site and they believe that they can order drugs

and that the drugs that they order on the Web site can be the very same drugs that they get down at the CVS or the Walgreens or the local community pharmacy.

Every time the FDA does an inspection at our international mail facilities, they discover anywhere from 67 to 90 percent of the drugs that are coming in from the orders of these mail sites, are either adulterated, misbranded or counterfeit drugs.

Now, let's just do the math. Every day, 20 to 30,000 packages, pharmaceutical packages enter each of our 12 international mail facilities every day. The FDA only screens less than 1 percent.

Now, let's think about this. Just take 30 days, for a month, times 400,000 packages, you get 12 million, times 12 months, that is 144 million pharmaceutical packages.

Now, do the math with regard to the number that are either misbranded, adulterated or counterfeit. Now, let's just do really simple math, and just say, okay, we will give a little flexibility in there. That is 100 million pharmaceutical packages that are either adulterated, misbranded or counterfeit. We have a very, very serious problem. Now, that is with regard to the human consumption.

Now, you are saying, STEVE, what does that have to do with the Animal Drug Fee User Act here today?

Well, what I had hoped to do is, it is only a matter of time before the bad actors of the world enter this economic space, meaning, if they can scam the American people with regard to human consumption, you know what? It is really going to be easier for them to do this in the animal drug business because you are never going to know why that animal died.

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We have a tremendous challenge. The FDA feels that they do not have the authority to destroy these misbranded, adulterated, or counterfeit drugs. So what's happening? You go to an international mail facility. When Customs finds one of those packages, they'll destroy it, but if that package then gets referred to the FDA, FDA feels that they do not have the legal authority to destroy that package.

Now when they feel they don't have the legal ability to destroy, they have adopted a “return-to-sender” policy.

Now let's think about this. The bad actors of the world, the counterfeiters and the criminal syndicates, are very sophisticated as to how they move these counterfeit packages from country to country to gain access into our marketplace. Then when we discover that package, the FDA, through their policy now, returns it to the counterfeiter. Think about that. Our own FDA that is there to protect us then becomes the enabler of the counterfeiter. So the counterfeiter takes the person's money and we return the merchandise that's counterfeit to the counterfeiter.

Now that is stupid. That's about as idiotic as I have ever seen.

So what did I attempt to do? Well, we're working on a food and drug safety bill in the committee, and I appreciate the gentlemen's work on both sides of the aisle. It's on human consumption. So what I had hoped to do here was say, Well, let's stop these bad actors and the criminal syndicates and the counterfeiters from entering into animal drugs. Chairman JOHN DINGELL agrees with that provision, and it was going to be in here.

The Democrat leadership said, "No. We can't have that in this bill." Now that's a curious and puzzling thing. But what I will say is, and my agreement with Chairman DINGELL is that this is an issue as a country in matters of food and drug safety that we, as Republicans and Democrats, must come together to protect the American people and to go after these bad actors around the world, the criminal syndicates who are preying upon America's most vulnerable populations. We have to enjoin together to do this. And that's my pledge to work with Chairman DINGELL and JOE BARTON and other members of the committee, and I salute Mr. MATHESON, for us to do this so not only do we bring protections on the animal side to go after the bad actors, we put protections in place on the human side. And we can do that not only in stopping the bad actors but also including electronic pedigree, and I will work with you to do just that.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

I just wanted to say that I understand the gentleman's concerns who just spoke, Mr. BUYER, the gentleman from Indiana, and I, too, am very concerned about counterfeit drugs entering the U.S. marketplace. I think the FDA should have the authority to seize and destroy counterfeit drugs. And as the gentleman knows, we are working with him to address this issue in a larger bill that will empower the FDA to protect the consumers from dangerous products, including counterfeit drugs. So I hope that we can continue to work with the gentleman on this matter.

Mr. BUYER. Will the gentleman yield?

Mr. PALLONE. I yield to the gentleman from Indiana.

Mr. BUYER. In my conversations with the chairman, not only last night but also this morning, I will work with the gentleman to make sure that we can have this in the drug safety bill not only on humans but will also protect animals, so we will give the authority to the FDA to destroy. I will work with the gentleman.

But we also brought up in the conversation—I understand that a little pain could have been created here today. I want to work with the majority. In other words, they weren't forced to go through the Rules Committee and then we have a big fight on the floor. I agreed with the chairman. We withdraw the amendment.

But I want to work also—please work with Mr. MATHESON and I on the electronic pedigree. It builds off of Chairman DINGELL's paper pedigree so we can sophisticate America's systems for American people here as we also then fight the counterfeiters who are trying to gain access into our market. And I'll work with the chairman to do that.

Mr. PALLONE. Mr. Speaker, I certainly heard what my colleague from Indiana said, and I'm certainly willing to work with him on what he's suggesting.

I reserve the balance of my time.

Mr. DEAL of Georgia. Mr. Speaker, I would also compliment Mr. BUYER for his sincere efforts on the issue of counterfeiting and look forward to working with him to address that issue both for humans and for animals in future legislation.

But because of the importance of this particular legislation and the need to reauthorize it in the time frame that is before us, I would urge the adoption of this legislation.

Mr. DINGELL. Mr. Speaker, I rise in support of H.R. 6432. Today we consider important public health legislation that, in the best tradition of the Committee on Energy and Commerce, has strong bipartisan support as well as backing from industry, consumer, and stakeholder groups.

I note that this bill has three titles—each representing different bills considered by the Committee on Energy and Commerce. The first title is the "Animal Drug User Fee Amendments of 2008". This title reauthorizes a successful user fee program that has allowed the Food and Drug Administration (FDA) to safely and efficiently review animal drugs. This part of the bill improves the existing program by increasing fee revenues, providing greater transparency, and setting specific timeframes by which data must be submitted to the FDA.

This title of the bill also contains provisions related to the issue of antimicrobial resistance. The Committee worked closely with Members from both sides of the aisle, as well as industry and consumer groups, to ensure that the FDA has the necessary information to examine safety concerns related to the use of antibiotics in food-producing animals. I commend Representatives MATHESON, WAXMAN, PALLONE, DEAL, and BARTON for reaching agreement on this important public health concern.

The next title is the "Animal Generic Drug User Fee Act of 2008" (AGDUFA). This program is similar in design to the ADUFA program, but with a specific focus on expediting the review of applications for new generic animal drugs.

A key component of both ADUFA and AGDUFA is additional resources for FDA to protect the public health. The lack of resources for the FDA has been a major focus of the Committee. I intend to address this issue more broadly in legislation being drafted with Representatives BARTON, DEAL, PALLONE, SHIMKUS, STUPAK, and others, that will significantly improve and enhance our food and drug safety system.

The third and final title makes two technical corrections to public law 110-85, the Food and Drug Administration Amendments Act of 2007. The first correction addresses an imple-

mentation problem related to the clinical trials results and registry database, which was expanded in that public law. The second correction clarifies that the FDA should review and approve generic drug applications separate and apart from citizen petitions pertaining to that application.

I encourage all of my colleagues to join me in support of this bill, and I thank the Members of the Committee on Energy and Commerce for working together to reach agreement on legislation critical to protecting the public health.

Mr. DEAL of Georgia. I would yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, again, I want to thank my colleagues on both sides of the aisle for their support of this legislation and urge that it be adopted.

I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 6432, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The title was amended so as to read: "A bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, to establish a program of fees relating to generic new animal drugs, to make certain technical corrections to the Food and Drug Administration Amendments Act of 2007, and for other purposes."

A motion to reconsider was laid on the table.

#### MICHELLE'S LAW

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2851) to amend the Employee Retirement Income Security Act of 1974, the Public Health Service Act, and the Internal Revenue Code of 1986 to ensure that dependent students who take a medically necessary leave of absence do not lose health insurance coverage, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 2851

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. SHORT TITLE.

This Act may be cited as "Michelle's Law".

#### SEC. 2. COVERAGE OF DEPENDENT STUDENTS ON MEDICALLY NECESSARY LEAVE OF ABSENCE.

##### (a) AMENDMENTS OF ERISA.—

(1) IN GENERAL.—Subpart B of part 7 of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following:

#### "SEC. 714. COVERAGE OF DEPENDENT STUDENTS ON MEDICALLY NECESSARY LEAVE OF ABSENCE.

"(a) MEDICALLY NECESSARY LEAVE OF ABSENCE.—In this section, the term 'medically necessary leave of absence' means, with respect to a dependent child described in subsection (b)(2) in connection with a group