were stored under unsafe conditions, or removed from their original packaging and mixed with other medication. Patients receiving these ''recycled'' medicines were at risk of contaminated or compromised drugs. Authorities estimate the large-scale drug diversion scheme cost the New York state Medicaid program almost half-billion dollars. Similar schemes in other states are well documented, including one in Tennessee earlier this year that cost the state Medicaid program more than $58 million.

In light of this ongoing and unacceptable risk to patients we urge the Energy and Commerce Subcommittee on Health to consider a strong unit-level serialization and traceability framework that appropriately secures and protects the distribution of medicines in the U.S. in a timely fashion. Thank you again for your work on this important issue.

American Public Health Association (APHA)
American Medical Women's Association
Annie Appleseed Project
Bladder Cancer Advocacy Network
Community Catalyst
Consumers Union
Fight Colorectal Cancer
International Myeloma Foundation
Lymphoma Research Foundation
National Association of County and City Health Officials (NACCHO)
National Women's Health Network
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Susan G. Komen
Trust for America's Health
U.S. PIRG

I would like to ask the gentleman from Ohio how many speakers he has?

Mr. LATTA. We have none.

Mr. WAXMAN. Mr. Speaker, I yield back the balance of my time.

Mr. LATTA. Mr. Speaker, we have no further speakers. I ask for support for the bill, and yield back the balance of my time.

Mr. DINGELL. Mr. Speaker, I rise today in support of H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013. The American people deserve peace of mind in knowing the pharmaceuticals they take every day are safe and have not been stolen, misbranded, or counterfeited. In last year's Food and Drug Administration Safety and Innovation Act, we took important steps to secure the upstream supply chain by ensuring FDA has accurate information about who is manufacturing and importing drugs, as well as requiring manufacturers to notify FDA if their pharmaceuticals may cause injury or death or have been stolen or counterfeited. That was a good first step, but now Congress must act to secure our downstream drug supply chain.

A strong, national track-and-trace system for our pharmaceutical supply chain will help improve public health and protect the American people from harm. We have seen far too many examples of counterfeit or unsafe pharmaceuticals entering the supply chain and ultimately ending up in the hands of patients. Now is the time to act and implement a system to trace pharmaceuticals as they move through the supply chain to prevent this from ever happening again. This system must be fair, feasible, and provide certainty to industry as to what is required of it. If done properly, a strong track-and-trace system will protect our pharmaceuticals from tampering and ensure their safety for patient use.

I want to thank my friends, Mr. MATHESON and Mr. LATTA, for their hard work on this important issue. I am the first to admit that this is not a perfect bill, and we have more work ahead of us. I also want to acknowledge the concerns of my friend and colleague from Maine, Mr. MICHAUD, about e-labeling. I commit to working with him to address this issue of great importance and ask that my colleagues do the same.

The Senate has also made real, bipartisan progress on this issue and taken a slightly different approach. I urge my colleagues to vote in favor of this legislation today to move the process forward on this matter. Congress has a clear opportunity to pass a bill with major benefits for the American people and must avail itself of the opportunity. I look forward to working with my colleagues on both sides of the aisle and both sides of Capitol Hill to send a strong, bi-partisan bill to President Obama.

Mr. PALLONE. Mr. Speaker, drug distribution security is critical to public health and safety, and I strongly support taking steps to ensure that the final pharmaceutical products patients receive are safe and effective. Although the bill before us today, H.R. 1919, the ''Safeguarding America's Pharmaceuticals Act,'' is well-intentioned, I have a number of concerns and believe the bill must be strengthened before it becomes law in order to truly protect the American people.

There is widespread agreement that the best way to protect the supply chain is to establish a unit-level, interoperable system that involves all members of the supply chain. However, under H.R. 1919, there is no assurance that an effective system for tracking and tracing drugs will ultimately be put into place. The bill only calls on FDA to issue proposed regulations—there is no requirement for final regulations.

In order to protect the drug supply chain, it is also important to ensure that unused drugs that are returned to the previous supplier and then re-enter the supply chain are just as safe as drugs going through the chain for the first time. I am concerned that the provisions in H.R. 1919, which allow the wholesaler to begin a new transaction history when it sells a returned product, create the potential for entry of illegitimate product into the system.

While I am pleased that H.R. 1919 sets national standards for the licensing of wholesale distributors, I am concerned that these standards preempt all state laws, effectively preventing states from having stronger licensing standards if they deem it necessary in their unique circumstance. National licensing standards should act as a floor defining what states must require, not as a floor and a ceiling.

I am also concerned that if H.R. 1919 becomes law, there will be a significant gap in the current level of information about a drug's path through the supply chain. H.R. 1919 preempts all state requirements regarding drug tracing on the date of enactment, but the new federal standards do not go into effect until 2015. This leaves a potentially-long window open for counterfeit or substandard products to enter the supply chain and reach customers.

It is crucial that if we are going to preempt state efforts, we must have a strong federal standard. This standard should serve as a true building block to tracking drugs at the unit level, so that each and every product is authenticated at the lowest unit of sale before they reach patients, and counterfeit or contaminated products are kept out of the drug supply chain or quickly eliminated from it. Unfortunately, H.R. 1919 does not meet these goals.

While I do not want to stop this process from moving forward, I remain concerned about the provisions in H.R. 1919 and look forward to conference with the Senate to strengthen the bill and, ultimately, enacting legislation that will truly protect the nation's drug supply.

Mr. PASCRELL. Mr. Speaker, as the House considers H.R. 1919, the Safeguarding America's Pharmaceuticals Act of 2013, I would like to voice my specific concerns with one provision within the legislation. While the underlying bill seeks to address the issue of preventing counterfeit drugs from reaching consumers, and improving national regulatory standards for pharmaceuticals, Section 8 of the proposed legislation instead mandates an electronic labeling requirement for pharmaceuticals. This serves to eliminate hard copy professional literature, and transition exclusively to electronic only literature. Based on legislation passed by Congress in 2012, GAO was tasked with studying the issue of e-labeling. This study is expected to be issued in July of this year. I urge my colleagues to carefully consider the potential ramifications of exclusive electronic labeling, and be cautious about any premature legislative action on this issue until the GAO report is released. The findings of this Congressionally mandated study should be deliberated before making a change that has the potential to impact consumers and providers.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Ohio (Mr. LATTA) that the House suspend the rules and pass the bill, H.R. 1919, as amended.

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

A motion to reconsider was laid on the table.

ANIMAL DRUG AND ANIMAL GENERIC DRUG USER FEE REAUTHORIZATION ACT OF 2013

Mr. LATTA. Mr. Speaker, I move to suspend the rules and pass the bill (S. 622) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 622

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 the ''Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013''.

SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

(a) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

(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.).

TITLE I—FEES RELATING TO ANIMAL DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Animal Drug User Fee Amendments of 2013''.

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

''SEC. 739. DEFINITIONS.

''For purposes of this part:

''(1) The term 'animal drug application' means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

''(2) The term 'supplemental animal drug application' means—

''(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

''(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

''(3) The term '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 animal drug application or a supplemental animal drug application has been approved.

''(4) The term 'animal drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

''(5) The term 'investigational animal drug submission' means—

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

''(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

''(6) The term 'animal drug sponsor' means 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.

''(7) The term 'final dosage form' means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

''(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) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

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

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

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

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

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

''(G) Meetings between the agency and the animal drug sponsor.

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

''(9) The term 'costs of resources allocated for the process for the review of animal drug applications' means the expenses in connection with the process for the review of animal drug applications 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 animal drug applications, supplemental animal drug applications, or investigational animal drug 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 section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(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 month being October 2002.

''(11) The term 'person' includes an affiliate thereof.

''(12) The term 'affiliate' refers to the definition set forth in section 735(11).''.

SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) is amended to read as follows:

''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 (c) for an animal drug application, except an animal drug application subject to the criteria set forth in section 512(d)(4).

''(ii) A fee established in subsection (c), 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) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

''(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug 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 animal drug application or supplemental animal drug application which is refused for filing.

''(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement 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 or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

''(2) ANIMAL DRUG PRODUCT FEE.—

''(A) IN GENERAL.—Each person—

''(i) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

''(ii) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall pay for each such animal drug product the annual fee established in subsection (c).

''(B) PAYMENT; FEE DUE DATE.—Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

''(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

''(ii) January 31 of each year.

''(C) LIMITATION.—Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

''(3) ANIMAL DRUG ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Each person—

''(i) who owns or operates, directly or through an affiliate, an animal drug establishment;

''(ii) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

''(iii) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual establishment fee as established in subsection (c) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application.

''(B) PAYMENT; FEE DUE DATE.—The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee under this paragraph for a fiscal year shall be due upon the later of—

''(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

''(ii) January 31 of each year.

''(C) LIMITATION.—

''(i) IN GENERAL.—An establishment shall be assessed only one fee per fiscal year under this section, subject to clause (ii).

''(ii) CERTAIN MANUFACTURERS.—If a single establishment manufactures both animal drug products and prescription drug products, as defined in section 735(3), such establishment shall be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 736(a)(2), within a single fiscal year.

''(4) ANIMAL DRUG SPONSOR FEE.—

''(A) IN GENERAL.—Each person—

''(i) who meets the definition of an animal drug sponsor within a fiscal year; and

''(ii) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug application, or an investigational animal drug submission,

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

''(B) PAYMENT; FEE DUE DATE.—The fee under this paragraph for a fiscal year shall be due upon the later of—

''(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

''(ii) January 31 of each year.

''(C) LIMITATION.—Each animal drug sponsor shall pay only one such fee each fiscal year.

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g)—

''(A) for fiscal year 2014, the fees required under subsection (a) shall be established to generate a total revenue amount of $23,600,000; and

''(B) for each of fiscal years 2015 through 2018, the fees required under subsection (a) shall be established to generate a total revenue amount of $21,600,000.

''(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

''(A) 20 percent shall be derived from fees under subsection (a)(1) (relating to animal drug applications and supplements);

''(B) 27 percent shall be derived from fees under subsection (a)(2) (relating to animal drug products);

''(C) 26 percent shall be derived from fees under subsection (a)(3) (relating to animal drug establishments); and

''(D) 27 percent shall be derived from fees under subsection (a)(4) (relating to animal drug sponsors).

''(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

''(1) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 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.

''(2) INFLATION ADJUSTMENT.—For fiscal year 2015 and subsequent fiscal years, the revenue amounts established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by an amount equal to the sum of—

''(A) one;

''(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available; and

''(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under this paragraph.

''(3) WORKLOAD ADJUSTMENT.—For fiscal year 2015 and subsequent fiscal years, after the revenue amounts established in subsection (b) are adjusted for inflation in accordance with paragraph (2), the revenue amounts shall be further adjusted for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of animal drug applications. With respect to such adjustment—

''(A) such adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary;

''(B) the Secretary shall publish in the Federal Register the fees resulting from such adjustment and the supporting methodologies; and

''(C) under no circumstances shall such 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 (2).

''(4) FINAL YEAR ADJUSTMENT.—For fiscal year 2018, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2019. If the Food and Drug Administration has carryover balances for the process for the review of 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 2018.

''(5) 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.

''(d) FEE WAIVER OR REDUCTION.—

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of one or more fees assessed under subsection (a) where the Secretary finds that—

''(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances;

''(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person;

''(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

''(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds; or

''(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation));

''(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication; or

''(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

''(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(B), the Secretary may use standard costs.

''(3) RULES FOR SMALL BUSINESSES.—

''(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

''(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

''(C) CERTIFICATION.—The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

''(e) EFFECT OF FAILURE TO PAY FEES.—An animal drug application or supplemental animal drug application 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 animal drug submission under section 739(5)(B) 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 animal drug application, supplemental animal drug application or investigational animal drug submission 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 2003 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 animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

''(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (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 2003 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 animal drug applications—

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

''(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

''(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

''(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2014 through 2018, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4).

''(4) OFFSET OF OVERCOLLECTIONS; RECOVERY OF COLLECTION SHORTFALLS.—

''(A) OFFSET OF OVERCOLLECTIONS.—If the sum of the cumulative amount of fees collected under this section for fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 (including any increased fee collections attributable to subparagraph (B)), exceeds the cumulative amount appropriated pursuant to paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.

''(B) RECOVERY OF COLLECTION SHORTFALLS.—

''(i) FISCAL YEAR 2016.—For fiscal year 2016, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2014 falls below the amount of fees authorized for fiscal year 2014 under paragraph (3).

''(ii) FISCAL YEAR 2017.—For fiscal year 2017, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2015 falls below the amount of fees authorized for fiscal year 2015 under paragraph (3).

''(iii) FISCAL YEAR 2018.—For fiscal year 2018, the amount of fees otherwise authorized to be collected under this section (including any reduction in the authorized amount under subparagraph (A)), shall be increased by the cumulative amount, if any, by which the amount collected under this section and appropriated for fiscal years 2016 and 2017 (including estimated collections for fiscal year 2017) falls below the cumulative amount of fees authorized under paragraph (3) for fiscal years 2016 and 2017.

''(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 animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(k) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—The Secretary shall—

''(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications; and

''(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.''.

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) is amended to read as follows:

''SEC. 740A. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to 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 101(b) of the Animal Drug User Fee Amendments of 2013 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 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report 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 2018, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

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

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

''(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, 2018, the Secretary shall transmit to Congress the revised recommendations under paragraph (4) a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

''(6) MINUTES OF NEGOTIATION MEETINGS.—

''(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

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

SEC. 105. SAVINGS CLAUSE.

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 October 1, 2008, but before October 1, 2013, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2014.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2013, or the date of enactment of this Act, whichever is later, except that 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 October 1, 2013, regardless of the date of the enactment of this Act.

SEC. 107. SUNSET DATES.

(a) AUTHORIZATION.—Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) shall cease to be effective October 1, 2018.

(b) REPORTING REQUIREMENTS.—Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) shall cease to be effective January 31, 2019.

(c) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 108 of the Animal Drug User Fee Amendments of 2008 (Public Law 110–316) is repealed.

(2) CONFORMING AMENDMENT.—The Animal Drug User Fee Amendments of 2008 (Public Law 110–316) is amended in the table of contents in section 1, by striking the item relating to section 108.

(d) TECHNICAL CLARIFICATION.—Effective November 18, 2003, section 5 of the Animal Drug User Fee Act of 2003 (Public Law 108–130) is repealed.

TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

SEC. 201. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Animal Generic Drug User Fee Amendments of 2013''.

(b) FINDING.—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. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

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

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

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

''(1) ABBREVIATED APPLICATION FEE.—

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

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

''(C) EXCEPTIONS.—

''(i) 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).

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

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

''(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an abbreviated application is withdrawn after the application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

''(2) GENERIC NEW ANIMAL DRUG PRODUCT FEE.—

''(A) IN GENERAL.—Each person—

''(i) who is named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product which has been submitted for listing under section 510; and

''(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application or supplemental abbreviated application,

shall pay for each such generic new animal drug product the annual fee established in subsection (c).

''(B) PAYMENT; FEE DUE DATE.—Such fee shall be payable for the fiscal year in which the generic new animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the generic new animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year,

such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

''(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

''(ii) January 31 of each year.

''(C) LIMITATION.—Such fee shall be paid only once for each generic new animal drug product for a fiscal year in which the fee is payable.

''(3) GENERIC NEW ANIMAL DRUG SPONSOR FEE.—

''(A) IN GENERAL.—Each person—

''(i) who meets the definition of a generic new animal drug sponsor within a fiscal year; and

''(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application, a supplemental abbreviated application, or an investigational submission,

shall be assessed an annual generic new animal drug sponsor fee as established under subsection (c).

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

''(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

''(ii) January 31 of each year.

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

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

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

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

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

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

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

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

''(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

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

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

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

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

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

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

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

''(f) ASSESSMENT OF FEES.—

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

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for abbreviated applications, generic new animal drug sponsors, and generic new animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of abbreviated applications for generic new animal drugs.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

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

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

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

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

''(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

''(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

''(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

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

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

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

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

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

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

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

''(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.

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

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration 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 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. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

''SEC. 742. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORTS.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Animal Generic Drug User Fee Amendments of 2013 toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs during such fiscal year.

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

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

''(d) REAUTHORIZATION.—

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

this part for such fiscal years, the Secretary shall consult with—

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

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

''(C) scientific and academic experts;

''(D) veterinary professionals;

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

''(F) the regulated industry.

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

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

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

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

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

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

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

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

''(B) publish such recommendations in the Federal Register;

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

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

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

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

''(6) MINUTES OF NEGOTIATION MEETINGS.—

''(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

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

SEC. 204. SAVINGS CLAUSE.

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

SEC. 205. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2013, or the date of enactment of this Act, whichever is later, except that fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this title, shall be assessed for all abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after October 1, 2013, regardless of the date of enactment of this Act.

SEC. 206. SUNSET DATES.

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

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

(c) PREVIOUS SUNSET PROVISION.—

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

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

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Ohio (Mr. LATTA) and the gentleman from California (Mr. WAXMAN) each will control 20 minutes.

The Chair recognizes the gentleman from Ohio.

GENERAL LEAVE

Mr. LATTA. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous material in the RECORD on the bill.

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

There was no objection.

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

I rise today in support of S. 622, the Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013. The Energy and Commerce Committee passed H.R. 1407, a nearly identical bill, through the committee last month with broad bipartisan support.

The agriculture industry, animal drug manufacturers, veterinarians, pet owners, and the Food and Drug Administration have all found both the Animal Drug User Fee and Animal Generic Drug User Fee to be very effective, and have asked Congress to reauthorize the programs as soon as possible. In addition, there is strong bipartisan support for the programs, which I think is a reflection of their success and effectiveness.

Passing S. 622 is extremely important for our Nation. First, having quality and safe medications is essential for ensuring the safety of our Nation's food supply chain. Second, these programs help livestock producers, poultry producers, and veterinarians keep their animals healthy. Third, these programs enable families to have safe and affordable drugs for their pets so they can live longer and healthier lives. It is essential that the House passes this bill swiftly so we can guarantee that these programs continue without interruption.

I would like to thank my colleagues, Mr. SHIMKUS and Mr. GARDNER, for their hard work on this very important piece of legislation. It is no small feat to move legislation to the President's desk in such an efficient manner.

I would also like to thank our colleagues in the Senate, including Senator HARKIN and Senator ALEXANDER, for their leadership.

Mr. Speaker, I support this bill, encourage my colleagues to do the same, and I reserve the balance of my time.

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

I rise in support of H.R. 1407, the Animal Drug User Fee Amendments of 2013. FDA's Animal Drug User Fee programs have been successful at speeding both brand and generic drugs for animals to the market, and that's important.

However, I regret that we have not taken this opportunity to provide FDA with new tools to address a glaring public health crisis—the problem of antibiotic resistance.

Antibiotics are truly a lifesaving gift. Unfortunately, the more they are used, the less they work. Untold numbers of Americans die or are infected each year by antibiotic-resistant bugs.

We know that most antibiotic use occurs on the farm, and much of this issue is not to treat sick animals, but most of the use is for disease prevention or growth promotion. If it's for treating sick animals, no one could quarrel with that. Unfortunately, if it's used for growth promotion or disease prevention, that is a misuse of it and could lead to antibiotic-resistant bugs.

We don't know exactly how much is for which of these two uses of the drug. That's why we need to ask industry to give us more data on how these drugs are being used, and to take steps to curtail the inappropriate use in animals of important human antibiotics.

My bill, the Delivering Antibiotic Transparency in Animals, or DATA, Act, would enhance the information FDA gets about how these drugs are used. Representative SLAUGHTER has a bill, which I have cosponsored, the Preservation of Antibiotics for Medical Treatment Act, or PAMTA, that would curtail the inappropriate use in animals of important human antibiotics.

We need to ensure that FDA not only has the resources and procedures for speeding safe and effective animal drugs to market, but also the information and tools to ensure that they are being used judiciously.

□ 1640

I regret that we are not taking this opportunity to give FDA these tools, but I hope we will soon have an opportunity to move these bills forward.

Mr. Speaker, I ask unanimous consent that the control of the time on my side of the aisle be given to the gentleman from North Carolina (Mr. BUTTERFIELD), and I reserve the balance of my time.

The SPEAKER pro tempore. Without objection, the gentleman from North Carolina will control the time.

There was no objection.

Mr. LATTA. Mr. Speaker, at this time, I yield 2 minutes to the chairman of the full committee, the gentleman from Michigan (Mr. UPTON).

Mr. UPTON. I rise today in strong support of S. 622, the Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013.

This bipartisan bill is nearly identical to H.R. 1407, which we favorably reported out of the Energy and Commerce Committee last month. This bill, as well as the Animal Generic Drug User Fee Act, has proven to be very successful; and they are so important for the Nation's public health. Congress first created ADUFA back in 2003 and AGDUFA in 2008. Collectively, these programs have yielded many benefits for the American public.

These two bills have ensured that veterinarians, livestock, poultry producers, and pet owners have access to new and affordable animal drugs to keep their animals healthy. They have assisted animal drug producers by fostering a stable and predictable FDA review process, a rigorous process that helps expedite access to new therapies and fosters new drug development. The programs have also helped American consumers by keeping the food supply safe. Having medications that keep our animals healthy is essential to keeping our Nation's food supply safe. For companies like Zoetis, which employs some 700 people in southwest Michigan, these programs are vital in allowing them to keep producing innovative drugs for pets and livestock.

I was the lead sponsor of the original ADUFA legislation back in 2003, and it is terrific to see how successful it has been and how many Americans it has helped over the last decade.

I want to thank my colleagues, particularly Mr. SHIMKUS and Mr. GARDNER, for their real leadership on this important issue. They deserve tremendous credit as we work to get this bill to the President's desk, and I urge my colleagues to support it.

Mr. BUTTERFIELD. Mr. Speaker, at this time, I yield such time as she may consume to the gentlelady from New York (Ms. SLAUGHTER).

Ms. SLAUGHTER. I thank my friend for yielding.

Mr. Speaker, just today, The New York Times reported that we are simultaneously facing a shortage of effective antibiotics and the growing threat of antibiotic-resistant bacteria. Already antibiotic-resistant disease claims 70,000 American lives each year.

According to today's story, Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research at the Food and Drug Administration, has warned ''it is bad now, and the infectious disease docs are frantic, but what is worse is the thought of where we will be 5 to 10 years from now.''

They are even desperate enough to ask GlaxoKleinSmith, which is working on some new antibiotics, to allow the use of them untested—the FDA is considering this—and to try, in perhaps what will turn out to be a vain attempt, to save people who are dying from infections that we can no longer cure. GlaxoKleinSmith has said the new antibiotics they are working on they will not license for livestock feed.

Eighty percent of the antibiotics produced in the United States of America is put every day in livestock feed. The major reason for the increase in the antibiotic-resistant bacteria is the routine overuse of antibiotics in the Nation's livestock. These are not sick livestock, Mr. Speaker. This is simply put in the feed because they grow faster and they are fatter and they can get to market a little quicker. This irresponsible practice has already been scientifically linked to the growth of superbugs.

It's clear—and it has been clear for quite a while—that the Federal Government must act to end this dangerous practice. Yet, incomprehensibly, for more than 35 years the United States Food and Drug Administration has refused to follow its own advice and ban the routine use of antibiotics in agriculture, not just use it for sick animals. Instead, they have proposed voluntary guidance that naively asks industry to put public welfare before private profits—something the industry has repeatedly shown in 35 years they will not do.

As if such dereliction of duty were not enough, the FDA is now panicked about the superbug threat that they helped to create; but instead of finally removing routine antibiotic use from livestock production, the FDA is thinking of waiving important drug-testing procedures, as I said, in order to rush new drugs to market. The testing procedures that are currently in place are in place for a reason. Waiving these requirements sets a dangerous precedent and is one that is only being considered because the FDA is panicked and has refused to challenge the special interests that have helped to create this superbug threat in the first place.

As the only legislator in Congress with a background in microbiology, I can assure you we will never win the arms race against nature. As long as we allow the irresponsible use of antibiotics in our society, nature will always evolve to create stronger bacteria. As I said, with 80 percent of all of the antibiotics going to agricultural use, our answer has to start on the farm. We have to end the unnecessary use of antibiotics on healthy animals before it's too late. Indeed, it may almost be too late.

At the very least today, the ADUFA legislation should include language to collect important data on antibiotics. That provision would at least allow us to finally learn the full scope of the problem that we confront. Even more importantly, I urge my colleagues to support my legislation, H.R. 1150, the Preservation of Antibiotics for Medical Treatment Act, which would ban the routine use of eight important classes of antibiotics in livestock, but still allow a sick animal to be treated, and would help curb the growing threat of superbugs.

We are literally standing today on the brink of a public health crisis as the food industrial complex fritters away one of the most important advances in medical history—the beginning of the use of antibiotics to cure human beings. Already, some strains of tuberculosis have evolved that are incurable, and others are coming. Some experts have said that if we don't do something soon—and it may already be too late—that strep throat could become a fatal illness. That's what they're worried about, what could happen here in 5 years.

I urge my colleagues to oppose this legislation today and to please join me in the fight to protect the antibiotics for human health. It is so important. I cannot vote for this bill, although I recognize that some work has gone into it. I have spent years on this, and the years are running out, and the time is short.

Mr. LATTA. Mr. Speaker, at this time, I yield 2 minutes to the chairman of the subcommittee, the gentleman from Pennsylvania (Mr. PITTS).

Mr. PITTS. I rise today in support of the reauthorization of two successful programs—the Animal Drug User Fee Act, ADUFA, and the Animal Generic Drug User Fee Act, AGDUFA.

The bill we have before us today originated in the Senate and was approved by unanimous consent on May 8, 2013; and I urge my colleagues in the House to support this legislation as well.

In 2003, the first ADUFA was authorized to help the Food and Drug Administration's review of animal drugs. Similar to the Prescription Drug User Fee for human drugs, under ADUFA, FDA collected funds to help expedite the new animal drug approval process, to reduce application backlog, and to improve communications with drug sponsors. The program was authorized for 5 years, and Congress renewed the program for an additional 5 years in ADUFA II in 2008. In 2012, FDA completed 747 ADUFA reviews; and, according to FDA, the agency has exceeded all performance goals outlined in ADUFA I and ADUFA II. However, absent congressional action, FDA's ability to collect these user fees will expire on September 30, 2013.

□ 1650

AGDUFA I, ADUFA's generic cousin, was first authorized in 2008 for 5 years in order to improve the review of abbreviated new animal drug applications, eliminate application backlogs, and reduce review times.

To date, according to FDA, the agency has exceeded all performance goals but one from AGDUFA I. This program also expires September 30, 2013, unless it is reauthorized and FDA and industry have negotiated an agreement for AGDUFA II. These programs are extremely important not only for our animals and livestock on our farms and ranches, but for our pets' health and well-being as well.

I want to thank my colleagues, Representative JOHN SHIMKUS and Representative CORY GARDNER, for their outstanding work on this legislation, and I urge my colleagues to support this important legislation.

Mr. BUTTERFIELD. I inquire as to whether the gentleman from Ohio has any additional speakers.

Mr. LATTA. We have one, Mr. Speaker.

Mr. BUTTERFIELD. Then I will reserve the balance of my time.

Mr. LATTA. Mr. Speaker, at this time I yield 2 minutes to the gentleman from Colorado (Mr. GARDNER).

Mr. GARDNER. Mr. Speaker, I thank the gentleman for yielding time.

I rise today in support of Senate Bill 622, the Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013.

This legislation will reauthorize two very important programs at the Food and Drug Administration that will provide farmers, ranchers, pet owners, and veterinarians with speedy access to medications that they need for the treatment of herds and pets.

I would like to thank Senator HARKIN for leading its passage in the U.S. Senate, and I would also like to thank Congressman SHIMKUS for his leadership with the House version of H.R. 1407.

These programs have been a success story at the FDA, and this legislation will ensure that drug approvals are done efficiently and to the highest quality standards. ADUFA and AGDUFA expire at the start of September, and we will need to pass this reauthorization today to assure there is no delay for animal caretakers and livestock producers. This bill will also help companies that develop and manufacture animal drugs by providing predictable time lines. It will also help them to benefit from a more stable review process so they can make decisions about where to invest research dollars.

Colorado has a thriving livestock industry which supports rural communities and economic strength for the entire State. I said this during the committee markup of H.R. 1407: there is more livestock in my district than people, or at least that's what I'm told. Colorado is also home to one of the Nation's premier schools of veterinary medicine at Colorado State University. Keeping livestock animals healthy, in particular, is crucial to ensuring our own health, not to mention the health of our family pets. The ADUFA and AGDUFA program keeps our food healthy and safe, while the application of animal drugs poses no risk to animal health.

I had the honor of introducing, with bipartisan support, H.R. 1408, the Animal Generic Drug User Fee Act, or AGDUFA. The bill was later incorporated into H.R. 1407. This program at FDA has achieved noteworthy success since first being authorized in 2008. The FDA has decreased a backlog of applications and reduced the review time for new generic drug applications. The reauthorization of this program will continue this success and allow our animal caretakers and livestock producers to utilize cost savings associated with generic medications.

Mr. BUTTERFIELD. Mr. Speaker, I ask if my friend has any further speakers on his side.

Mr. LATTA. I have none.

Mr. BUTTERFIELD. As we have no further speakers either, Mr. Speaker, I yield back the balance of my time.

Mr. LATTA. Mr. Speaker, I ask for passage of S. 622, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I rise in strong support of S. 622, the Animal Drug and Animal Generic Drug User Fee Reauthorization Act.

Congress enacted the Animal Drug User Fee Act (ADUFA) in 2003 to help improve the FDA review of new animal drugs, and subsequently enacted the Animal Generic Drug User Fee Act (AGDUFA) to improve the review of abbreviated new animal drug applications, or generic versions of animal drugs. These programs have been extremely effective, and have helped expedite the approval process, reduce application backlogs, and improve communications with drug sponsors.

Without congressional action, the current agreements will expire at the end of this fiscal year, which would have a serious and harmful impact on the ability of the FDA's Center for Veterinary Medicine to review new and generic drug applications in a timely manner. S. 622 will extend FDA's authority to collect user fees from manufacturers for five years.

I urge my colleagues to vote in favor of S. 622, so that progress is not impeded and the Food and Drug Administration can continue to review new and generic animal drug applications in a timely manner. Industry, farmers, ranchers, and pet owners are counting on an uninterrupted supply of animal drugs.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Ohio (Mr. LATTA) that the House suspend the rules and pass the bill, S. 622.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. BUTTERFIELD. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this motion will be postponed.

COROLLA WILD HORSES PROTECTION ACT

Mr. WITTMAN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 126) to direct the Secretary of the Interior to enter into an agreement to provide for management of the free-roaming wild horses in and around the Currituck National Wildlife Refuge.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 126

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 the ''Corolla Wild Horses Protection Act''.

SEC. 2. WILD HORSES IN AND AROUND THE CURRITUCK NATIONAL WILDLIFE REFUGE.

(a) AGREEMENT REQUIRED.—

(1) IN GENERAL.—The Secretary of the Interior shall enter into an agreement with the Corolla Wild Horse Fund (a nonprofit corporation established under the laws of the State of North Carolina), the County of Currituck, North Carolina, and the State of North Carolina within 180 days after the date of enactment of this Act to provide for management of free-roaming wild horses in and around the Currituck National Wildlife Refuge.

(2) TERMS.—The agreement shall—

(A) allow a herd of not less than 110 and not more than 130 free-roaming wild horses in and around such refuge, with a target population of between 120 and 130 free-roaming wild horses;

(B) provide for cost-effective management of the horses while ensuring that natural resources within the refuge are not adversely impacted;

(C) provide for introduction of a small number of free-roaming wild horses from the herd at Cape Lookout National Seashore as is necessary to maintain the genetic viability of the herd in and around the Currituck National Wildlife Refuge; and

(D) specify that the Corolla Wild Horse Fund shall pay the costs associated with—

(i) coordinating a periodic census and inspecting the health of the horses;

(ii) maintaining records of the horses living in the wild and in confinement;

(iii) coordinating the removal and placement of horses and monitoring of any horses removed from the Currituck County Outer Banks; and

(iv) administering a viable population control plan for the horses including auctions, adoptions, contraceptive fertility methods, and other viable options.

(b) REQUIREMENTS FOR INTRODUCTION OF HORSES FROM CAPE LOOKOUT NATIONAL SEASHORE.—During the effective period of the memorandum of understanding between the National Park Service and the Foundation for Shackleford Horses, Inc. (a non-profit corporation organized under the laws of and doing business in the State of North Carolina) signed in 2007, no horse may be removed from Cape Lookout National Seashore for introduction at Currituck National Wildlife Refuge except—

(1) with the approval of the Foundation; and

(2) consistent with the terms of such memorandum (or any successor agreement) and the Management Plan for the