HR 5554

Animal Drug and Animal Generic Drug User Fee Amendments of 2018

Congress: 115 (2017–2019, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 18, 2018
Current Status: Became Public Law No: 115-234.
Latest Action: Became Public Law No: 115-234. (Aug 14, 2018)
Law: 115-234 (Enacted Aug 14, 2018)
Official Text: https://www.congress.gov/bill/115th-congress/house-bill/5554

Sponsor

Name: Rep. Mullin, Markwayne [R-OK-2]
Party: Republican • **State:** OK • **Chamber:** Senate

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Apr 18, 2018
Rep. Green, Gene [D-TX-29]	D · TX		Apr 18, 2018
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Apr 18, 2018
Rep. Schrader, Kurt [D-OR-5]	D · OR		Apr 18, 2018
Rep. Walden, Greg [R-OR-2]	R · OR		Apr 18, 2018

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported by	Apr 25, 2018

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
115 S 2434	Related bill	**Mar 7, 2018:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 341.

Animal Drug and Animal Generic Drug User Fee Amendments of 2018

TITLE I--FEES RELATING TO ANIMAL DRUGS

This bill addresses the authority of the Food and Drug Administration (FDA) to collect new animal drug (brand name animal drug) and generic animal drug user fees.

Animal Drug User Fee Amendments of 2018

(Sec. 103) The bill amends the Federal Food, Drug, and Cosmetic Act to reauthorize through FY2023 the authority of the FDA to collect and use brand name animal drug user fees.

The FDA must not collect fees for (1) supplemental applications that are submitted solely to add the animal drug application number to the label of the drug, and (2) applications for genetically engineered animals that are intended to produce human medical products.

The bill revises the total amount of revenue brand name animal drug user fees can generate.

The bill also revises the requirements for calculating adjustments to revenue amounts based on changes in the workload for reviewing brand name animal drug applications.

(Sec. 104) The bill extends requirements for the FDA to report to Congress on achieving goals related to the animal drug development and review processes and implementation of the authority to collect brand name animal drug user fees.

(Sec. 107) The bill terminates the authority of the FDA to collect brand name animal drug user fees on October 1, 2023.

TITLE II--FEES RELATING TO GENERIC ANIMAL DRUGS

Animal Generic Drug User Fee Amendments of 2018

(Sec. 202) The bill reauthorizes through FY2023 the authority of the FDA to collect and use generic animal drug user fees. The FDA must not collect fees for supplemental abbreviated applications that are submitted solely to add the generic animal drug application number to the label of the drug.

The bill revises the total amount of revenue each type of generic animal drug user fee must generate.

The bill also revises the requirements for calculating adjustments to revenue amounts based on changes in the workload for reviewing generic animal drug applications.

(Sec. 203) The bill extends requirements for the FDA to report to Congress on achieving goals related to the generic animal drug development and review process and the implementation of the authority to collect generic animal drug fees.

(Sec. 206) The bill terminates the authority of the FDA to collect generic animal drug user fees on October 1, 2023.

TITLE III--MISCELLANEOUS PROVISIONS

(Sec. 301) Brand name and generic animal drug applications must be submitted electronically beginning in FY2019. Additionally, applications for conditional approval of brand name animal drugs for minor use and minor species must be

submitted electronically beginning in FY2019. (Minor use drugs are for intended uses in major species [horses, dogs, cats, cattle, pigs, turkeys, and chickens] for diseases that occur infrequently or in limited geographic areas and in only a small number of animals annually.)

(Sec. 302) Product labeling for certain unapproved brand name animal drugs for minor species must include the index number in order to be marketed.

(Sec. 303) The bill prohibits the sale of brand name animal drugs that do not include the FDA application number.

(Sec. 304) The bill authorizes the FDA to grant conditional approval of a brand name animal drug not intended for a minor use or minor species if (1) the drug is intended to treat a serious or life-threatening disease or condition or addresses an unmet animal or human health need, and (2) the FDA determines that a demonstration of effectiveness of the drug would require a complex or particularly difficult study or studies.

The FDA must issue guidance or regulations that provide further details regarding the criteria for conditional approval.

The bill terminates this conditional approval authority on October 1, 2028.

The Government Accountability Office must study the effects of the conditional approval pathway for brand name animal drugs.

(Sec. 305) The FDA must issue guidance on how to evaluate certain elements of investigations as part of the animal drug application process, and how drug sponsors may obtain feedback from the agency on technical issues before submitting an application.

(Sec. 306) The FDA must review investigations conducted in foreign countries when acting on a petition for a food additive intended for use in animal food.

The FDA must also issue guidance on the voluntary pre-petition consultation process for such food additives.

Actions Timeline

- **Aug 14, 2018:** Signed by President.
- **Aug 14, 2018:** Became Public Law No: 115-234.
- **Aug 3, 2018:** Presented to President.
- **Aug 1, 2018:** Message on Senate action sent to the House.
- **Jul 31, 2018:** Passed/agreed to in Senate: Passed Senate without amendment by Voice Vote.(consideration: CR S5474)
- **Jul 31, 2018:** Passed Senate without amendment by Voice Vote. (consideration: CR S5474)
- **Jul 17, 2018:** Received in the Senate, read twice.
- **Jul 16, 2018:** Mr. Mullin moved to suspend the rules and pass the bill, as amended.
- **Jul 16, 2018:** Considered under suspension of the rules. (consideration: CR H6237-6242)
- **Jul 16, 2018:** DEBATE - The House proceeded with forty minutes of debate on H.R. 5554.
- **Jul 16, 2018:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.(text: CR H6237-6241)
- **Jul 16, 2018:** On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. (text: CR H6237-6241)
- **Jul 16, 2018:** Motion to reconsider laid on the table Agreed to without objection.
- **May 9, 2018:** Committee Consideration and Mark-up Session Held.
- **May 9, 2018:** Ordered to be Reported (Amended) by Voice Vote.
- **Apr 25, 2018:** Referred to the Subcommittee on Health.
- **Apr 25, 2018:** Subcommittee Consideration and Mark-up Session Held.
- **Apr 25, 2018:** Forwarded by Subcommittee to Full Committee (Amended) by Voice Vote .
- **Apr 18, 2018:** Introduced in House
- **Apr 18, 2018:** Referred to the House Committee on Energy and Commerce.