S 622

Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013

Congress: 113 (2013–2015, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 20, 2013
Current Status: Became Public Law No: 113-14.
Latest Action: Became Public Law No: 113-14. (Jun 13, 2013)
Law: 113-14 (Enacted Jun 13, 2013)
Official Text: https://www.congress.gov/bill/113th-congress/senate-bill/622

Sponsor

Name: Sen. Harkin, Tom [D-IA]
Party: Democratic • **State:** IA • **Chamber:** Senate

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported Original Measure	Mar 20, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
113 HR 1407	Related bill	**Aug 2, 2013:** Placed on the Union Calendar, Calendar No. 135.
113 HR 1408	Related bill	**Apr 12, 2013:** Referred to the Subcommittee on Health.

Summary (as of Jun 13, 2013)

(This measure has not been amended since it was introduced. The expanded summary of the Senate reported version is repeated here.)

Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013 - **Title I: Fees Relating to Animal Drugs** - Animal Drug User Fee Amendments of 2013 - (Sec. 103) Amends the Federal Food, Drug, and Cosmetic Act to extend for FY2014-FY2018 the authority of the Food and Drug Administration (FDA) to collect animal drug user fees, specifically new animal drug application or supplemental animal drug application fees, animal drug product fees, animal drug establishment fees, and animal drug sponsor fees.

Revises the due date for annual user fees to the later of January 31 of each year or the first business day after enactment of an appropriations act providing for the collection and obligation of fees for the fiscal year.

Establishes the amount of revenue such fees can generate. Specifies percentages of the total revenue that shall be derived from each type of user fee.

Requires the Secretary of Health and Human Services (HHS) to adjust the total revenue amounts for FY2015 and subsequent fiscal years for inflation.

Authorizes the Secretary to accept payment of user fees prior to their due date.

Requires the total fees collected for FY2016-FY2018 to be increased by the cumulative amount, if any, by which the amount of user fees collected and appropriated for prior fiscal year falls below the cumulative amount of fees authorized.

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

(Sec. 107) Terminates the authority to collect user fees October 1, 2018.

Title II: Fees Relating to Generic Animal Drugs - Animal Generic Drug User Fee Amendments of 2013 - (Sec. 202) Extends for FY2014-FY2018 the authority of the FDA to collect generic animal drug user fees, specifically abbreviated application fees for generic new animal drugs, generic new animal drug product fees, and generic new animal drug sponsor fees.

Subjects generic animal drug applications to a fee 50% of the amount of the normal fee if the application is for an animal drug which contains more than one active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with one or more other animal drugs, and the active ingredients or drugs intended for use in the combination have previously been separately approved.

Revises the due date for annual generic animal drug user fees to the later of January 31 of each year or the first business day after enactment of an appropriations act providing for the collection and obligation of fees for the fiscal year.

Establishes the total amount of revenue each type of generic user fee shall generate.

Authorizes the Secretary to accept payment of user fees prior to their due date.

(Sec. 203) 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) Terminates the authority to collect generic animal drug user fees October 1, 2018.

Actions Timeline

- **Jun 13, 2013:** Signed by President.
- **Jun 13, 2013:** Became Public Law No: 113-14.
- **Jun 6, 2013:** Presented to President.
- **Jun 3, 2013:** Mr. Latta moved to suspend the rules and pass the bill.
- **Jun 3, 2013:** Considered under suspension of the rules. (consideration: CR H2984-2993)
- **Jun 3, 2013:** DEBATE - The House proceeded with forty minutes of debate on S. 622.
- **Jun 3, 2013:** At the conclusion of debate, the Yeas and Nays were demanded and ordered. Pursuant to the provisions of clause 8, rule XX, the Chair announced that further proceedings on the motion would be postponed.
- **Jun 3, 2013:** Considered as unfinished business. (consideration: CR H3001)
- **Jun 3, 2013:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 390 - 12 (Roll no. 185).(text: CR H2984-2991)
- **Jun 3, 2013:** On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 390 - 12 (Roll no. 185). (text: CR H2984-2991)
- **Jun 3, 2013:** Motion to reconsider laid on the table Agreed to without objection.
- **May 9, 2013:** Received in the House.
- **May 9, 2013:** Message on Senate action sent to the House.
- **May 9, 2013:** Held at the desk.
- **May 8, 2013:** Passed/agreed to in Senate: Passed Senate without amendment by Unanimous Consent.(consideration: CR S3275-3282; text as passed Senate: CR S3275-3282)
- **May 8, 2013:** Passed Senate without amendment by Unanimous Consent. (consideration: CR S3275-3282; text as passed Senate: CR S3275-3282)
- **Mar 20, 2013:** Introduced in Senate
- **Mar 20, 2013:** Committee on Health, Education, Labor, and Pensions. Original measure reported to Senate by Senator Harkin. Without written report.
- **Mar 20, 2013:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 31.