HR 1407

Animal Drug User Fee Amendments of 2013

Congress: 113 (2013–2015, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 9, 2013
Current Status: Placed on the Union Calendar, Calendar No. 135.
Latest Action: Placed on the Union Calendar, Calendar No. 135. (Aug 2, 2013)
Official Text: https://www.congress.gov/bill/113th-congress/house-bill/1407

Sponsor

Name: Rep. Shimkus, John [R-IL-15]
Party: Republican • **State:** IL • **Chamber:** House

Cosponsors (8 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Apr 9, 2013
Rep. Gardner, Cory [R-CO-4]	R · CO		Apr 9, 2013
Rep. Guthrie, Brett [R-KY-2]	R · KY		Apr 9, 2013
Rep. Kinzinger, Adam [R-IL-16]	R · IL		Apr 9, 2013
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Apr 9, 2013
Rep. Pitts, Joseph R. [R-PA-16]	R · PA		Apr 9, 2013
Rep. Upton, Fred [R-MI-6]	R · MI		Apr 9, 2013
Rep. Waxman, Henry A. [D-CA-33]	D · CA		Apr 9, 2013

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Discharged from	May 14, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
113 S 622	Related bill	**Jun 13, 2013:** Became Public Law No: 113-14.

Summary (as of Aug 2, 2013)

Title I: Animal Drug User Fee Amendments - 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: Animal Generic Drug User Fee Amendments - 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

- **Aug 2, 2013:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 113-188.
- **Aug 2, 2013:** Placed on the Union Calendar, Calendar No. 135.
- **May 15, 2013:** Committee Consideration and Mark-up Session Held.
- **May 15, 2013:** Ordered to be Reported by Voice Vote.
- **May 14, 2013:** Subcommittee on Health Discharged.
- **May 14, 2013:** Committee Consideration and Mark-up Session Held.
- **Apr 12, 2013:** Referred to the Subcommittee on Health.
- **Apr 9, 2013:** Introduced in House
- **Apr 9, 2013:** Referred to the House Committee on Energy and Commerce.