HR 1408

Animal Generic Drug User Fee Amendments of 2013

Congress: 113 (2013–2015, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 9, 2013
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Apr 12, 2013)
Official Text: https://www.congress.gov/bill/113th-congress/house-bill/1408

Sponsor

Name: Rep. Gardner, Cory [R-CO-4]
Party: Republican • **State:** CO • **Chamber:** Senate

Cosponsors (8 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Burgess, Michael C. [R-TX-26]	R · TX		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. Shimkus, John [R-IL-15]	R · IL		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	Referred to	Apr 12, 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 Apr 9, 2013)

Animal Generic Drug User Fee Amendments of 2013 - Amends the Federal Food, Drug, and Cosmetic Act to extend for FY2014-FY2018 the authority of the Food and Drug Administration (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 of Health and Human Services (HHS) to accept payment of user fees prior to their due date.

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.

Terminates the authority to collect generic animal drug user fees October 1, 2018.

Actions Timeline

- **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.