HR 6432

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the animal drug user fee program, to establish a program of fees relating to generic new animal drugs, to make certain technical corrections to the Food and Drug Administration Amendments Act of 2007, and for other purposes.

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
Introduced: Jul 8, 2008
Current Status: Became Public Law No: 110-316.
Latest Action: Became Public Law No: 110-316. (Aug 14, 2008)
Law: 110-316 (Enacted Aug 14, 2008)
Official Text: https://www.congress.gov/bill/110th-congress/house-bill/6432

Sponsor

Name: Rep. Pallone, Frank, Jr. [D-NJ-6]
Party: Democratic • **State:** NJ • **Chamber:** House

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Barton, Joe [R-TX-6]	R · TX		Jul 8, 2008
Rep. Deal, Nathan [R-GA-9]	R · GA		Jul 8, 2008
Rep. Dingell, John D. [D-MI-15]	D · MI		Jul 8, 2008
Rep. Towns, Edolphus [D-NY-10]	D · NY		Jul 8, 2008
Rep. DeGette, Diana [D-CO-1]	D · CO		Jul 10, 2008

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported by	Jul 9, 2008

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Aug 14, 2008)

(This measure has not been amended since it was passed by the House on July 30, 2008. The summary of that version is repeated here.)

Title I: Animal Drug User Fee Amendments - Animal Drug User Fee Amendments of 2008 - (Sec. 102) Amends the Federal Food, Drug, and Cosmetic Act to revise definitions, including defining the "process for the review of animal drug applications" to include the review of advertising and labeling prior to an approval of an animal drug application or supplemental animal application after the animal drug has been approved.

(Sec. 103) Requires the Secretary of Health and Human Services to assess 50% of the standard fee for a new animal drug application for a drug that combines active ingredients that have been approved separately.

Sets forth the amount of revenue that animal drug application fees, supplemental and other animal drug application fees, product fees, establishment fees, and sponsor fees are to generate for FY2009-FY2013.

(Sec. 104) Requires the Secretary to report to Congress and make publicly available information on: (1) progress toward the goal of expediting the animal drug development process and the review of animal drug applications; and (2) implementation of the authority for and use of animal drug fees.

Sets forth a process for the Secretary to develop recommendations for the process of review of animal drug applications after FY2013.

(Sec. 105) Requires the sponsor of any new animal drug that contains an antimicrobial active ingredient to annually report to the Secretary on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. Authorizes the Secretary to share such information with the Antimicrobial Resistance Task Force.

(Sec. 108) Terminates the authority to collect and assess animal drug fees on October 1, 2013. Terminates reporting requirements on January 31, 2014.

Title II: Animal Generic Drug User Fee - Animal Generic Drug User Fee Act of 2008 - (Sec. 202) Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary to assess and collect fees for an abbreviated application for a generic new animal drug, including application fees, product fees, and sponsor fees.

Sets forth total revenue to be collected for each type of fee for FY2009-FY2013.

Provides for fee adjustments. Requires the Secretary to establish such fees each fiscal year.

Provides for fee waivers where the Secretary finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.

Authorizes appropriations for FY2009-FY2013.

(Sec. 203) Requires the Secretary to report to Congress and make publicly available information on: (1) progress toward the goal of expediting the generic new animal drug development process and the review of abbreviated applications for such drugs; and (2) the implementation of the authority for and use of generic new animal drug fees.

Sets forth the process for developing recommendations to present to Congress for the review of abbreviated applications

for generic new animal drugs after FY2013.

(Sec. 204) Terminates the authority to assess and use generic new animal drug fees on October 1, 2013. Terminates reporting requirements on January 31, 2014.

Title III: Technical Corrections to FDAAA - (Sec. 301) Amends the Federal Food, Drug, and Cosmetic Act to require that consideration of a citizen petition or a petition for a stay of agency action on a new drug application be separate and apart from review and approval of any such application.

(Sec. 302) Amends the Public Health Service Act to make technical corrections to provisions related to the clinical trials data bank.

Actions Timeline

- **Aug 14, 2008:** Signed by President.
- **Aug 14, 2008:** Became Public Law No: 110-316.
- **Aug 6, 2008:** Presented to President.
- **Aug 1, 2008:** Passed/agreed to in Senate: Passed Senate without amendment by Unanimous Consent.(consideration: CR S7984)
- **Aug 1, 2008:** Passed Senate without amendment by Unanimous Consent. (consideration: CR S7984)
- **Aug 1, 2008:** Message on Senate action sent to the House.
- **Aug 1, 2008:** Cleared for White House.
- **Jul 31, 2008:** Received in the Senate, read twice.
- **Jul 30, 2008:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 110-804.
- **Jul 30, 2008:** Placed on the Union Calendar, Calendar No. 520.
- **Jul 30, 2008:** Mr. Pallone moved to suspend the rules and pass the bill, as amended.
- **Jul 30, 2008:** Considered under suspension of the rules. (consideration: CR H7534-7541)
- **Jul 30, 2008:** DEBATE - The House proceeded with forty minutes of debate on H.R. 6432.
- **Jul 30, 2008:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.(text: CR H7534-7539)
- **Jul 30, 2008:** On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. (text: CR H7534-7539)
- **Jul 30, 2008:** Motion to reconsider laid on the table Agreed to without objection.
- **Jul 30, 2008:** The title of the measure was amended. Agreed to without objection.
- **Jul 16, 2008:** Committee Consideration and Mark-up Session Held.
- **Jul 16, 2008:** Ordered to be Reported (Amended) by Voice Vote.
- **Jul 9, 2008:** Subcommittee Consideration and Mark-up Session Held.
- **Jul 9, 2008:** Forwarded by Subcommittee to Full Committee by Voice Vote .
- **Jul 8, 2008:** Introduced in House
- **Jul 8, 2008:** Referred to the House Committee on Energy and Commerce.
- **Jul 8, 2008:** Referred to the Subcommittee on Health.