

HR 1260

Animal Drug User Fee Act of 2003

Congress: 108 (2003–2005, Ended)

Chamber: House

Policy Area: Health

Introduced: Mar 13, 2003

Current Status: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and

Latest Action: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Oct 2, 2003)

Official Text: <https://www.congress.gov/bill/108th-congress/house-bill/1260>

Sponsor

Name: Rep. Upton, Fred [R-MI-6]

Party: Republican • **State:** MI • **Chamber:** House

Cosponsors (20 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Bilirakis, Michael [R-FL-9]	R · FL		Mar 13, 2003
Rep. DeGette, Diana [D-CO-1]	D · CO		Mar 13, 2003
Rep. Greenwood, James C. [R-PA-8]	R · PA		Mar 13, 2003
Rep. John, Christopher [D-LA-7]	D · LA		Mar 13, 2003
Rep. Towns, Edolphus [D-NY-10]	D · NY		Mar 13, 2003
Rep. Otter, C. L. (Butch) [R-ID-1]	R · ID		Mar 20, 2003
Rep. Pickering, Charles W. "Chip" [R-MS-3]	R · MS		Mar 26, 2003
Rep. Boswell, Leonard L. [D-IA-3]	D · IA		Apr 10, 2003
Rep. Gilchrest, Wayne T. [R-MD-1]	R · MD		Apr 10, 2003
Rep. Whitfield, Ed [R-KY-1]	R · KY		Apr 10, 2003
Rep. Putnam, Adam H. [R-FL-12]	R · FL		May 6, 2003
Rep. Rogers, Mike J. [R-MI-8]	R · MI		May 6, 2003
Rep. Deal, Nathan [R-GA-10]	R · GA		May 15, 2003
Rep. Souder, Mark E. [R-IN-3]	R · IN		May 15, 2003
Rep. Boucher, Rick [D-VA-9]	D · VA		May 19, 2003
Rep. Terry, Lee [R-NE-2]	R · NE		May 19, 2003
Rep. Moran, Jerry [R-KS-1]	R · KS		Jun 2, 2003
Rep. Thornberry, Mac [R-TX-13]	R · TX		Jun 26, 2003
Rep. Chocola, Chris [R-IN-2]	R · IN		Sep 4, 2003
Rep. Goodlatte, Bob [R-VA-6]	R · VA		Sep 30, 2003

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 24, 2003
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Oct 2, 2003

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
108 S 313	Related bill	Nov 18, 2003: Became Public Law No: 108-130.

(This measure has not been amended since it was introduced. The summary has been expanded because action occurred on the measure.)

Animal Drug User Fee Act of 2003 - (Sec. 3) Amends the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to assess and collect fees for an animal drug application, defined as a request for approval of a new animal drug (not including generic drugs). Directs the Secretary to also assess fees for a supplemental animal drug application, defined as a request for a change in an approved animal drug application or in an approved generic animal drug application (if it requires safety or effectiveness data). Requires payment upon submission or the application will be considered incomplete and not accepted. Excepts from payment applications which were previously filed but withdrawn or not approved without a waiver or refund.

Assesses annual fees on animal drug products, establishments, and sponsors. Declares that only one such fee per category must be paid each year.

Establishes a fee schedule for FY 2004 through 2008, including total fee revenues for animal drug products, establishments, and sponsors. Adjusts fees to reflect inflation, review workload, and operating reserves of carryover user fees (in the final year).

Directs the Secretary to establish before each fiscal year, based on the fee schedule revenue amounts and the adjustments, the following: (1) animal drug application fees and supplemental animal drug application fees (for applications in which safety or effectiveness data are required); (2) animal drug sponsor fees; (3) animal drug establishment fees; and (4) animal drug product fees. Reduces or waives fees: (1) in excess of administrative costs; (2) that present a significant barrier to innovation; (3) if an animal drug application or supplemental animal drug application is intended solely for use of an animal drug in specified types of feed; (4) if an animal drug application or supplemental animal drug application is intended solely to provide for minor uses or use in minor species; or (5) for first applications by a small business.

Makes fees available for obligation only to the extent provided in advance in appropriations Acts. Authorizes appropriations. Offsets any excess fees against subsequent appropriations.

(Sec. 4) Establishes public accountability and reporting requirements.

(Sec. 5) Establishes a sunset date of October 1, 2008, for the provisions of this Act not pertaining to public accountability and reports and a sunset date of 120 days after such date for such accountability and reporting provisions.

Actions Timeline

- **Oct 2, 2003:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **Oct 1, 2003:** Mr. Upton moved to suspend the rules and pass the bill.
- **Oct 1, 2003:** Considered under suspension of the rules. (consideration: CR H9054-9059)
- **Oct 1, 2003:** DEBATE - The House proceeded with forty minutes of debate on H.R. 1260.
- **Oct 1, 2003:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by voice vote.(text: CR H9054-9057)
- **Oct 1, 2003:** On motion to suspend the rules and pass the bill Agreed to by voice vote. (text: CR H9054-9057)
- **Oct 1, 2003:** Motion to reconsider laid on the table Agreed to without objection.
- **Sep 30, 2003:** Reported by the Committee on Energy and Commerce. H. Rept. 108-287.
- **Sep 30, 2003:** Reported by the Committee on Energy and Commerce. H. Rept. 108-287.
- **Sep 30, 2003:** Placed on the Union Calendar, Calendar No. 167.
- **Sep 10, 2003:** Committee Consideration and Mark-up Session Held.
- **Sep 10, 2003:** Ordered to be Reported by Voice Vote.
- **Mar 24, 2003:** Referred to the Subcommittee on Health.
- **Mar 13, 2003:** Introduced in House
- **Mar 13, 2003:** Introduced in House
- **Mar 13, 2003:** Sponsor introductory remarks on measure. (CR E462)
- **Mar 13, 2003:** Referred to the House Committee on Energy and Commerce.