

S 313

Animal Drug User Fee Act of 2003

Congress: 108 (2003–2005, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Feb 5, 2003

Current Status: Became Public Law No: 108-130.

Latest Action: Became Public Law No: 108-130. (Nov 18, 2003)

Law: 108-130 (Enacted Nov 18, 2003)

Official Text: https://www.congress.gov/bill/108th-congress/senate-bill/313

Sponsor

Name: Sen. Ensign, John [R-NV]

Party: Republican • State: NV • Chamber: Senate

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Gregg, Judd [R-NH]	R · NH		Feb 5, 2003
Sen. Harkin, Tom [D-IA]	D · IA		Feb 5, 2003
Sen. Kennedy, Edward M. [D-MA]	D · MA		Feb 5, 2003
Sen. Lugar, Richard G. [R-IN]	R · IN		May 19, 2003

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 11, 2003
Health, Education, Labor, and Pensions Committee	Senate	Reported By	May 21, 2003

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
108 HR 1260	Related bill	Oct 2, 2003: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

(This measure has not been amended since it was passed by the House on November 4, 2003. The summary of that version is repeated here.)

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 Excepts from payment applications which were previously filed but withdrawn or not approved without a waiver or refund.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

- **Nov 18, 2003:** Signed by President.
- **Nov 18, 2003:** Signed by President.
- **Nov 18, 2003:** Became Public Law No: 108-130.
- **Nov 18, 2003:** Became Public Law No: 108-130.
- **Nov 12, 2003:** Presented to President.
- **Nov 12, 2003:** Presented to President.
- **Nov 10, 2003:** Message on Senate action sent to the House.
- **Nov 7, 2003:** Resolving differences -- Senate actions: Senate agreed to House amendment by Unanimous Consent.(consideration: CR S14279-14282; text as Senate agreed to House amendment: CR S14279-14282)
- **Nov 7, 2003:** Senate agreed to House amendment by Unanimous Consent. (consideration: CR S14279-14282; text as Senate agreed to House amendment: CR S14279-14282)
- **Nov 5, 2003:** Message on House action received in Senate and at desk: House amendment to Senate bill.
- **Nov 4, 2003:** Mr. Upton moved to suspend the rules and pass the bill, as amended.
- **Nov 4, 2003:** Considered under suspension of the rules. (consideration: CR H10293-10297)
- **Nov 4, 2003:** DEBATE - The House proceeded with forty minutes of debate on S. 313.
- **Nov 4, 2003:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.(text: CR H10293-10296)
- **Nov 4, 2003:** On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. (text: CR H10293-10296)
- **Nov 4, 2003:** Motion to reconsider laid on the table Agreed to without objection.
- **Jun 11, 2003:** Referred to the Subcommittee on Health.
- **Jun 4, 2003:** Message on Senate action sent to the House.
- **Jun 4, 2003:** Received in the House.
- **Jun 4, 2003:** Referred to the House Committee on Energy and Commerce.
- **Jun 3, 2003:** Senate vitiated previous passage.
- **Jun 3, 2003:** Measure laid before Senate by unanimous consent. (consideration: CR S7266)
- **Jun 3, 2003:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.
- **Jun 3, 2003:** Passed Senate with an amendment by Unanimous Consent.
- **May 23, 2003:** Passed/agreed to in Senate: Passed Senate with amendments by Unanimous Consent.(consideration: CR S7165-7171; text as passed Senate: CR H7168-7171; text of measure as reported in Senate: CR S7165-7168)
- **May 23, 2003:** Passed Senate with amendments by Unanimous Consent. (consideration: CR S7165-7171; text as passed Senate: CR H7168-7171; text of measure as reported in Senate: CR S7165-7168)
- **May 21, 2003:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Gregg with amendments. With written report No. 108-51.
- **May 21, 2003:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Gregg with amendments. With written report No. 108-51.
- **May 21, 2003:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 104.
- **Feb 12, 2003:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Feb 5, 2003:** Introduced in Senate
- **Feb 5, 2003:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.