

S 1844

Animal Drug and Animal Generic Drug User Fee Amendments of 2023

Congress: 118 (2023–2025, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jun 7, 2023

Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 174.

Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 174. (Jul 26, 2023)

Official Text: <https://www.congress.gov/bill/118th-congress/senate-bill/1844>

Sponsor

Name: Sen. Baldwin, Tammy [D-WI]

Party: Democratic • **State:** WI • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Mullin, Markwayne [R-OK]	R · OK		Jun 7, 2023

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Jul 26, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 HR 6687	Related bill	Dec 8, 2023: Referred to the Subcommittee on Health.
118 HR 5860	Related bill	Sep 30, 2023: Became Public Law No: 118-15.
118 HR 1418	Related bill	Sep 20, 2023: Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 210.
118 S 1842	Related bill	Jun 7, 2023: Read twice and referred to the Committee on Agriculture, Nutrition, and Forestry.

Animal Drug and Animal Generic Drug User Fee Amendments of 2023

This bill reauthorizes the Food and Drug Administration (FDA) to collect fees for brand-name and generic animal drug applications through FY2028. It also makes related updates to fee calculations and FDA reporting requirements.

The bill also (1) provides for a specific fee for requests to establish generic investigational new animal drug files and requires other application fees to be adjusted accordingly; (2) authorizes the FDA to remove species from the definition of *major species* (currently horses, dogs, cats, cattle, pigs, chickens, and turkeys); (3) provides statutory authority for the FDA to report on its progress supporting antimicrobial stewardship in veterinary settings (i.e., supporting responsible use of antimicrobial drugs for animals to slow the development of drug-resistant bacteria); and (4) provides for the regulation of zootechnical animal food substances as food additives (zootechnical animal food substances are added to the food or drinking water of animals to affect the byproducts of the animal's digestion, reduce foodborne pathogens, or alter the animal's gastrointestinal biome).

Animal drugs are drugs that are intended for animals other than humans (e.g., pets and livestock). Animal drugs must be approved by the FDA before they may be offered on the commercial market. The FDA is authorized to collect fees for animal drug applications in order to support its regulatory activities; this authority currently expires at the end of FY2023.

Actions Timeline

- **Jul 26, 2023:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Sanders with an amendment. Without written report.
- **Jul 26, 2023:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 174.
- **Jun 15, 2023:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment favorably.
- **Jun 7, 2023:** Introduced in Senate
- **Jun 7, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.