

S 741

Minor Use and Minor Species Animal Health Act of 2003

Congress: 108 (2003–2005, Ended)

Chamber: Senate

Policy Area: Animals

Introduced: Mar 27, 2003

Current Status: Became Public Law No: 108-282.

Latest Action: Became Public Law No: 108-282. (Aug 2, 2004)

Law: 108-282 (Enacted Aug 2, 2004)

Official Text: <https://www.congress.gov/bill/108th-congress/senate-bill/741>

Sponsor

Name: Sen. Sessions, Jeff [R-AL]

Party: Republican • **State:** AL • **Chamber:** Senate

Cosponsors (21 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Allard, Wayne [R-CO]	R · CO		Mar 27, 2003
Sen. Bingaman, Jeff [D-NM]	D · NM		Mar 27, 2003
Sen. Collins, Susan M. [R-ME]	R · ME		Mar 27, 2003
Sen. Craig, Larry E. [R-ID]	R · ID		Mar 27, 2003
Sen. Crapo, Mike [R-ID]	R · ID		Mar 27, 2003
Sen. Ensign, John [R-NV]	R · NV		Mar 27, 2003
Sen. Gregg, Judd [R-NH]	R · NH		Mar 27, 2003
Sen. Harkin, Tom [D-IA]	D · IA		Mar 27, 2003
Sen. Lincoln, Blanche L. [D-AR]	D · AR		Mar 27, 2003
Sen. Miller, Zell [D-GA]	D · GA		Mar 27, 2003
Sen. Shelby, Richard C. [R-AL]	R · AL		Apr 10, 2003
Sen. Domenici, Pete V. [R-NM]	R · NM		May 13, 2003
Sen. Enzi, Michael B. [R-WY]	R · WY		May 14, 2003
Sen. Smith, Gordon H. [R-OR]	R · OR		May 22, 2003
Sen. Murray, Patty [D-WA]	D · WA		Jul 9, 2003
Sen. Hatch, Orrin G. [R-UT]	R · UT		Jul 15, 2003
Sen. Landrieu, Mary L. [D-LA]	D · LA		Jul 29, 2003
Sen. Wyden, Ron [D-OR]	D · OR		Sep 2, 2003
Sen. Pryor, Mark L. [D-AR]	D · AR		Sep 23, 2003
Sen. Durbin, Richard J. [D-IL]	D · IL		Feb 2, 2004
Sen. Cantwell, Maria [D-WA]	D · WA		Feb 25, 2004

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported by	Jun 15, 2004
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Feb 18, 2004

Subjects & Policy Tags

Policy Area:

Animals

Related Bills

Bill	Relationship	Last Action
108 HR 2079	Related bill	May 20, 2003: Referred to the Subcommittee on Health.

(This measure has not been amended since it was reported to the Senate on February 18, 2004. The summary of that version is repeated here.)

Title I: Minor Use and Minor Species Health – Minor Use and Minor Species Animal Health Act of 2004 - (Sec. 102)

Amends the Federal Food, Drug, and Cosmetic Act regarding the development of new animal drugs intended for a minor use (defines "minor use" as the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals, or in limited geographic areas and in only a small number of animals annually) or for use in a minor species (any species other than cattle, horses, swine, chickens, turkeys, dogs, and cats).

Allows the Food and Drug Administration (FDA) to award three years of market exclusivity, with full approval, for any new animal drug that requires research to be conducted in the targeted minor species to support such approval.

Creates a conditional approval process for new animal drugs intended for a minor use or for use in a minor species. Requires the same standards for approval as the full approval, except that there must only be a reasonable expectation that the drug is effective for use. (Full approval requires adequate and well-controlled studies to demonstrate by substantial evidence that a new animal drug is effective.) Requires sponsors to commit to conducting additional investigation to meet the full requirements for the demonstration of effectiveness within five years. Establishes that a conditional approval is renewable annually for up to four additional one-year terms upon submission of a request for renewal. Requires labels of such drugs to bear a statement identifying the new animal drug as conditionally approved.

Requires the Secretary of Health and Human Services to establish an index of legally-marketed, unapproved new animal drugs for use in minor species. Provides that this index lists drugs that are not FDA-approved and that are either: (1) not intended for use in animals that will be consumed by humans or by food-producing animals; or (2) not intended for use in early, non-food life stages of food-producing minor species, unless safety for humans has been adequately demonstrated. Specifies labeling requirements for indexed drugs.

Allows the Secretary, before submission of an application for drug approval, to designate new minor use or minor species animal drugs. Provides: (1) grants for such designated drugs for qualified safety and effectiveness testing, and for manufacturing expenses incurred in connection with further development of such drugs; and (2) market exclusivity for such drugs for seven years, with specified exceptions. Requires the Secretary to terminate any such designation if the sponsor discontinues active pursuit of approval.

Directs the Secretary to establish within the Center for Veterinary Medicine of FDA an Office of Minor Use and Minor Species Animal Drug Development to: (1) designate minor use and minor species animal drugs; (2) administer grants and contracts; (3) review minor species drug index listing requests; and (4) serve as a liaison to other government agencies interested in minor use and minor species animal drug development.

Title II: Food Allergen Labeling and Consumer Protection - Food Allergen Labeling and Consumer Protection Act of 2004 - (Sec. 203) Amends the Federal Food, Drug, and Cosmetic Act to require a food that contains, or is derived from, a major food allergen to indicate that information on its label. Defines "major food allergen" as any of the following: milk, eggs, fish, Crustacea, tree nuts, wheat, peanuts, and soybeans. Provides that the labeling requirement must be met by stating the common or usual name of the food allergen in the list of ingredients or by other methods allowed by the Secretary. Requires allergens in flavoring, coloring, or incidental additives to also be labeled in accordance with these requirements.

(Sec. 204) Requires the Secretary to issue a report to Congress that: (1) analyzes the ways in which foods are unintentionally contaminated with major food allergens during manufacturing and processing; (2) estimates how common this contamination is; (3) advises whether good manufacturing practices or other methods can be used to reduce or eliminate this contamination; (4) describes the various types of advisory labels used by food processors, the manufacturing conditions associated with these labels, and the extent to which such labels are used; (5) describes how consumers with food allergies would prefer contamination information to be provided; (6) describes the inspections that have occurred and the violations discovered; and (7) assesses the extent to which contamination has been effectively addressed.

(Sec. 205) Directs the Secretary to inspect facilities to ensure that the facilities comply with practices to reduce or eliminate contamination and properly label food allergens.

(Sec. 206) Requires the Secretary to define and permit use of the term "gluten-free" on food labels.

(Sec. 207) Directs the Secretary, acting through the Director of the Centers for Disease Control, to improve the collection of, and publish national data on, the prevalence of food allergies, the incidence of serious adverse events related to food allergies, and the use of different modes of treatment for and prevention of allergic responses to food. Authorizes appropriations.

(Sec. 208) Requires the Secretary, acting through the Director of the National Institutes of Health, to convene a panel of nationally recognized experts to review basic and clinical research efforts related to food allergies and to recommend ways to enhance and coordinate research activities concerning food allergies.

(Sec. 209) Directs the Secretary, in the Conference for Food Protection, to pursue certain revisions of the Food Code to provide guidelines for preparing allergen-free foods in food establishments.

(Sec. 210) Requires the Secretary to include technical assistance on the use of different modes of treatment for, and prevention of, allergic responses with the technical assistance provided to States and local agencies relating to trauma care and emergency medical services.

Actions Timeline

- **Aug 2, 2004:** Signed by President.
- **Aug 2, 2004:** Signed by President.
- **Aug 2, 2004:** Became Public Law No: 108-282.
- **Aug 2, 2004:** Became Public Law No: 108-282.
- **Jul 23, 2004:** Presented to President.
- **Jul 23, 2004:** Presented to President.
- **Jul 20, 2004:** Mr. Pickering moved to suspend the rules and pass the bill.
- **Jul 20, 2004:** Considered under suspension of the rules. (consideration: CR H6093-6101)
- **Jul 20, 2004:** DEBATE - The House proceeded with forty minutes of debate on S. 741.
- **Jul 20, 2004:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by voice vote.(text: CR H6093-6099)
- **Jul 20, 2004:** On motion to suspend the rules and pass the bill Agreed to by voice vote. (text: CR H6093-6099)
- **Jul 20, 2004:** Motion to reconsider laid on the table Agreed to without objection.
- **Jul 15, 2004:** Reported by the Committee on Energy and Commerce. H. Rept. 108-608.
- **Jul 15, 2004:** Reported by the Committee on Energy and Commerce. H. Rept. 108-608.
- **Jul 15, 2004:** Placed on the Union Calendar, Calendar No. 366.
- **Jun 24, 2004:** Committee Consideration and Mark-up Session Held.
- **Jun 24, 2004:** Ordered to be Reported by Voice Vote.
- **Jun 15, 2004:** Subcommittee Consideration and Mark-up Session Held.
- **Jun 15, 2004:** Forwarded by Subcommittee to Full Committee by Voice Vote.
- **Mar 11, 2004:** Referred to the Subcommittee on Health.
- **Mar 9, 2004:** Message on Senate action sent to the House.
- **Mar 9, 2004:** Received in the House.
- **Mar 9, 2004:** Referred to the House Committee on Energy and Commerce.
- **Mar 8, 2004:** The committee substitute agreed to by Unanimous Consent. (consideration: CR S2365-2375; text of measure as reported in Senate: CR S2365-2374)
- **Mar 8, 2004:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.
- **Mar 8, 2004:** Passed Senate with an amendment by Unanimous Consent.
- **Feb 18, 2004:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Gregg under authority of the order of the Senate of February 12, 2004 with an amendment in the nature of a substitute. With written report No. 108-226.
- **Feb 18, 2004:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Gregg under authority of the order of the Senate of February 12, 2004 with an amendment in the nature of a substitute. With written report No. 108-226.
- **Feb 18, 2004:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 431.
- **Nov 21, 2003:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Mar 27, 2003:** Introduced in Senate
- **Mar 27, 2003:** Sponsor introductory remarks on measure. (CR S4530-4531)
- **Mar 27, 2003:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.