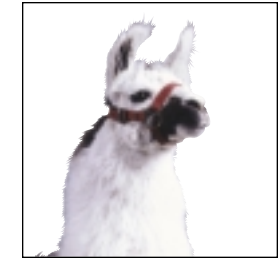


Legislative History

- 1996** Congress passes Animal Drug Availability Act (ADAA) that requires FDA to propose ways to improve the availability of drugs for minor uses and minor species
- 1997** FDA seeks public comment on documents including a "Discussion Draft: Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses"
- 1998** FDA concludes federal statutes should be amended in report "Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses"
- 1999-2000** MUMS Coalition established; uses FDA proposals and technical assistance to develop draft legislation
- 2001** The Minor Use and Minor Species Animal Health Act is introduced



M U M S
Improving Animal Health

Solutions to a Critical Need
Drugs for Minor Uses and Minor Species

Minor Use and Minor Species Animal Health Act

In the United States there is a critical shortage of approved animal drugs intended for less common animal species or those with less common conditions. Very few animal drugs for these indications exist, or what drugs do exist may not be used legally in those animals that need the therapeutics. Therefore veterinarians, animal owners, and livestock producers may have limited options for treating these animals if they become ill. The shortage of approved drugs results in animal suffering, loss of animal life, and financial loss to those who raise the animals.

The Minor Use and Minor Species (MUMS) Animal Health Act of 2001 is similar to the human Orphan Drug Act of 1983. It is intended as a mechanism to provide FDA-authorized drugs for those less common species and indications. Specifically, it seeks to provide labeled drugs for needy *minor species*, including sheep, goats, game birds, emus, ranched deer, alpacas, llamas, deer, elk, rabbits, guinea pigs, pet birds, reptiles, ornamental and other fish, shellfish, wildlife, zoo and aquaria animals. The MUMS Act is designed to provide *major species* (cats, dogs, horses, cattle, swine, turkey, chickens) with needed therapeutics for uncommon indications, so called *minor uses*.

The MUMS Act will allow companies the opportunity to develop and market FDA-authorized drugs that are vital to a large number of animal species. The Act will alleviate unnecessary animal suffering and dying. It will promote the health and well being of animals while protecting and assuring human health. It will benefit pets in the home and comfort the families that care for them. The MUMS Act will benefit various endangered species, zoo animals and wildlife populations. The Act will reduce economic risks and hardships to farmers and ranchers, and enhance the global competitiveness of our nation's animal producers.



Benefits of the MUMS Act

- allow companies the opportunity to develop and market FDA-authorized drugs that are vital to a large number of animal species
- alleviate unnecessary animal suffering and dying
- promote the health and well being of animals while protecting and assuring human health
- benefit pets in the home and comfort the families that care for them
- benefit various endangered species, zoo animals and wildlife populations.
- reduce economic risks and hardships to farmers and ranchers
- enhance the global competitiveness of our nation's animal producers.

Protecting the Public Health

The MUMS Act incorporates significant proposals made by the FDA Center for Veterinary Medicine to increase the availability of drugs to treat minor species and other species with uncommon conditions. The bill contains mechanisms to enhance the health of animals while maintaining the rigorous public safety requirements of the FDA. The Act does not alter the FDA's obligation to see that the food we eat is safe, and drugs are labeled truthfully with the information that people need to use them properly.

Furthermore, inadequate treatment of sick animals because of a shortage of FDA-authorized drugs may increase public health hazards. The transmission of parasites or pathogens from animals to humans, or the shedding of disease-producing organisms by untreated animals into the environment, may increase health risks to humans as well as other animals.



Legislative Background

Congress recognized that statutory changes might be needed to address the described shortage of approved animal drugs in the Animal Drug Availability Act (ADAA) (Public Law 104-250), passed in 1993. A section of the legislation recognized particular problems relating to the availability of approved animal drugs for minor uses in major species and for use in minor species. The law directed the Secretary of Health and Human Services to consider and announce proposals for legislative or regulatory change to the approval process for such drugs. The FDA concluded that federal statutes should be amended and the FDA proposals provide the conceptual base for the Minor Use and Minor Species Animal Health Act of 2001.

MUMS Coalition

The Minor Use and Minor Species (MUMS) Coalition is a diverse group of veterinarians, animal owners and producers, and developers of animal products that share an interest in animal health and have consolidated to assist the FDA to address the common need of increasing the legal availability of animal drugs for minor species and minor uses.

Members represent terrestrial and aquatic animals, domestic and wild animals, and those kept as pets, livestock, zoological and aquaria collections, and animals in rehabilitation and restoration programs.

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