



December 5, 2005

AMERICAN ZOO AND  
AQUARIUM ASSOCIATION

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Division of Dockets Management, HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No. 2005N-0329. Proposed Rule: Designation of New Animal  
Drugs for Minor Uses or Minor Species

Dear Docket Manager:

The American Zoo and Aquarium Association (AZA) respectfully submits the following comments concerning Docket No. 2005N-0329. Proposed Rule: Designation of New Animal Drugs for Minor Uses or Minor Species.

AZA supports the scope and intent of the proposed rule as promulgated by the Food and Drug Administration (FDA). AZA strongly supports incentives that encourage pharmaceutical companies to develop drugs needed for the health and welfare of minor animal species and to develop drugs needed to treat infrequent diseases of animals.

AZA is a non-profit organization dedicated to the advancement of zoos and aquariums in the areas of animal care and husbandry, conservation, education, science and recreation. AZA's vision, and that of its member institutions, is to work cooperatively within and between institutions, as well as with threatened and endangered species' range countries around the world, to save and protect the wonders of our living natural world.

AZA represents 210 professionally-managed and accredited institutions which draw over 142 million visitors annually and have more than 8 million zoo and aquarium members. Expert staff employed by AZA-accredited zoos and aquariums are the foremost authorities and practitioners of animal care and well-being; are deeply involved in their local communities through outreach and education programs; and have a profound and abiding commitment to conservation education, conservation science and field research.

AZA is the leader in establishing and maintaining high standards for zoos and aquariums through our accreditation process. Accreditation is a detailed review and peer inspection covering all aspects of an institution's operation including animal

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care and husbandry, veterinary care, physical facilities, safety, security, finance, staffing, governing authority, support organizations, education programs, conservation and research and adherence to local, state and federal laws.

*AZA Specific Comments*

In the proposed rule, the term “minor species” is generally defined as any animal not classified as a major species which includes “cattle, horses, swine, chickens, turkeys, dogs and cats...” We are concerned that many zoo animals may be included in these broad species categories. For example, we have concerns as to whether the major species designation of "cattle" includes all *Bos taurus* subspecies (ankole, zebu, etc) as opposed to purely agricultural breeds common to the United States. Without such distinctions, this might impact whether or not a proposed drug would be appropriate for development under MUMS.

In addition, the broad designation of “cattle” raises concerns that there may be a number of drugs that cannot be used legally in agricultural cattle thereby precluding MUMS approval or indexing of these drugs for use in exotic or nonagricultural subspecies/breeds of cattle.

*AZA recommends that FDA specifically identify what species and subspecies are considered “major species” with the recognition that some species/subspecies may be appropriate only for public display or exhibition. These non-domestic animals should be identified separately for appropriate drug approval under MUMS regulations.*

As FDA continues to formulate future policies to address the issue of minor use/minor species, I strongly encourage the agency to call upon the informational resources and expertise of the American Zoo and Aquarium Association. Our resources can assist the agency in developing effective, common-sense measures that can help protect wildlife in the U.S. and abroad.

Thank you for the opportunity to review and comment on this important rule.

Regards,



Steven G. Olson  
Director of Government Affairs