

# AMDUCA

*From pages 6-7 of the Magnesium Hydroxide TAP*

## **FDA PUBLISHES FINAL RULE ON EXTRALABEL DRUG USE IN ANIMALS**

In the November 7, 1996 *Federal Register*, FDA published a final rule to allow veterinarians to prescribe extralabel uses of certain approved animal drugs and approved human drugs for animals under certain conditions. This action implements the Animal Drug Use Clarification Act of 1994 (AMDUCA). This regulation provides veterinarians with greater flexibility in the use of approved drugs in animals. These regulations put AMDUCA into effect on December 9, 1996.

The notice of proposed rulemaking published in the *Federal Register* on May 17, 1996. FDA received and considered approximately 110 comments in preparing the final rule.

Prior to the enactment of AMDUCA, the Federal Food, Drug, and Cosmetic Act (the Act) required users of approved new animal drug products to follow the exact directions on the labeling of the drug. This extralabel use restriction precluded use of an approved drug in species or for indications (disease or other

conditions) not listed in the labeling, use of an approved drug at dosage levels higher than those stated on the label, and other extralabel purposes. In addition, the Act did not provide for the use of human drugs for treating animals.

Because of AMDUCA, the Federal Food, Drug, and Cosmetic Act will now permit veterinarians, like physicians, to prescribe extralabel uses of approved drugs for their patients. Although certain restrictions have been placed on veterinarians prescribing animal and human drugs in an extralabel manner, these restrictions generally apply only to the use of drugs extralabelly in food-producing animals. The key constraints are that any extralabel use must not result in violative residues in food-producing animals, the use must be by or on the order of a veterinarian within the context of a veterinarian-client-patient relationship, and the use must be in conformance with the new regulations.

AMDUCA includes a number of provisions that permit the Agency to restrict extralabel use in certain circumstances. For example, if there is a finding that there is a reasonable probability that an extralabel use may present a risk to public health from drug residues in animal-derived food, the Agency may establish a safe level for a residue for such extralabel use by regulation or order and may require the development of analytical methods for residue detection. If, after affording an opportunity for public comment, FDA finds that an extralabel animal drug use presents a risk to public health or that no analytical method has been developed and submitted, the Agency may prohibit such extralabel use. The following prohibitions currently apply to the uses of drugs in food-producing animals:

Chloramphenicol  
Clenbuterol  
Diethylstilbestrol (DES)  
Dimetridazole  
Ipronidazole  
Other nitroimidazoles  
Furazolidone (except for approved topical use)  
Nitrofurazone (except for approved topical use)  
Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine and sulfaethoxyypyridazine)

Neither AMDUCA nor the implementing regulations are intended to lessen the responsibility of the manufacturer, the veterinarian, or the food producer with regard to drug residues. Under AMDUCA, any amount of residue resulting from an extralabel use would constitute a violation of the Act if a safe level or tolerance has not been established.

Title 21 of the *Code of Federal Regulations* is now amended to add a new part 530, titled "Extralabel Drug Use in Animals."<sup>1</sup>

Magnesium Hydroxide/Oxide is allowed for extralabel animal used in food-producing animals because it is not explicitly prohibited.

<sup>1</sup> Information was copied directly from <http://www.fda.gov/cvm/index/amducca/amducatoc.htm>

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