
RESOLUTION NUMBER: 6 APPROVED

SOURCE: COMMITTEE ON WILDLIFE

SUBJECT MATTER: Food and Drug Administration Draft Guidance for Industry #256

BACKGROUND INFORMATION:

The United States Food and Drug Administration (FDA) recently provided Draft Guidance for Industry #256, "Compounding Animal Drugs from Bulk Drug Substances". In this document, FDA describes situations in which action would not be taken for violations of the Food, Drug, and Cosmetic Act (FDCA), specifically as it relates to the compounding of animal drugs from bulk drug substances. Under the Animal Medicinal Drug Use Clarification Act (AMDUCA), compounding of animal drugs, including for food animals, from approved human or animal drugs is explicitly permitted. Until this guidance document was released, it was understood that compounding drugs from bulk substances or active pharmaceutical ingredients was also permitted when no other approved drug formulation was available or effective.

According to this guidance document, the FDA will not seek enforcement action for compounding of drugs from bulk drug substances when they are prescribed for a specific patient or group of patients of non-food animal species, when they are maintained as office stock for use in non-food animal species to treat urgent conditions and to manage pain and suffering, or when they will be used as antidotes in food animal species. The guidance document also requires that any compound that will be used as office stock or as an antidote in food animals be provided to the FDA with supporting documentation for approval. It is not feasible for the wildlife veterinary community to provide the required information for the growing number of essential active pharmaceutical ingredients for each of the species in which they will be used.

At the same time, the FDA recognizes that there are situations in which an approved human or animal drug is not available to properly treat a patient's condition. Wildlife veterinarians are concerned that many of the species treated are considered food animals and that the drugs compounded from bulk drug substances used in these species are essential to address public safety, as well as animal safety, health, and welfare. Furthermore, these drugs are most often compounded by regulated compounding pharmacies using certified ingredients and good manufacturing practices. If these drugs are not available, wildlife management activities, human and animal safety, animal health, and wildlife resources will be negatively affected.

RESOLUTION:

The United States Animal Health Association urges the United States Food and Drug Administration (FDA) to add the use of medications compounded from bulk drug substances by licensed compounding pharmacies for free-ranging and rehabilitated wildlife to the situations or conditions under which the FDA would not pursue enforcement action against the compounding pharmacy or prescribing veterinarian.