FDA Must Issue Final Guidance on Animal Drug Compounding

Summary

FDA released new draft Guidance for Industry #256 on animal drug compounding. This guidance has long been needed to clarify the line between animal compounding from bulk drug substances that will be permitted by enforcement discretion and that which remains illegal.

Background

Compounding is the manipulation of a drug to make a different drug to meet the needs of a particular patient. For example, mixing two injectable drugs or adding flavor to a commercially available drug is compounding. Under the Animal Medicinal Drug Use Clarification Act (AMDUCA), compounding of animal preparations is legal when done using an FDA-approved drug pursuant to a prescription from a licensed veterinarian for a specific patient.This type of compounding is not affected by Guidance #256 and will continue to be used by veterinarians to meet the needs of patients.

Compounding animal preparations from bulk drug substances is illegal. However, because not all active pharmaceutical ingredients needed to treat veterinary patients are available in approved products, FDA's Center for Veterinary Medicine (CVM) has used enforcement discretion to allow compounding from bulk to meet these medical needs.

Some large compounding pharmacies have taken advantage of this situation and use bulk drug substances as active ingredients to produce large batches of drugs without a veterinary prescription. These products are often copies or near copies of approved drugs and have not been tested for safety or efficacy like FDA approved drugs. Studies show compounded products often contain too much or too little active ingredient. Errors in the preparation and use of these compounded products have resulted in at least three instances of multiple horses across several states dying or being euthanized due to the harm caused by these products.

FDA's new draft Guidance for Industry #256 protects the health and welfare of animals and humans by establishing a mechanism to define the specific bulk substances and the circumstances under which they can be used to compound animal products. This guidance has long been needed to curtail the illegal activity of compounders acting like drug manufacturers, placing animal health at risk.

This guidance protects veterinarians and pet owners by ensuring they are fully informed about the legality and safety evaluations of the products they prescribe and give their pets. It is intended to ensure pharmacies can use compounding to meet veterinary patient needs but not act like manufacturers and market products that undermine the FDA approval process and put animal health at risk.

Status

FDA is ready to publish this final guidance after considering all comments that have been submitted. However, misinformation around what the guidance will and will not do is circulating. Our goal is to assist FDA in setting the record straight to enable the agency to publish final guidance to enhance the safety of animal compounding.

AHI/GADA Position

The animal health industry supports legal compounding as described in AMDUCA and supports the use of bulk drug substances for compounding when no active ingredient needed to address patient conditions is found in an approved product. Specific guidance to describe these situations where FDA will permit compounding from bulk substances is a critical need addressed by this guidance, and it should be finalized.

Request

AHI and GADA request Members of Congress to contact FDA's CVM to support finalization of draft Guidance for Industry #256 on Animal Drug Compounding and to provide adequate enforcement resources in order to protect animal health.

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