Myth vs. Fact: Animal Drug Compounding

Compounding animal drug preparations to address disease conditions in animals is an integral part of veterinary medicine.

The animal health industry supports:

- Compounding as permitted by federal law
- FDA's use of enforcement discretion to allow compounding from bulk substances where active ingredients needed to address animal conditions are not present in approved products
- Guidance that clearly describes the line between compounding from bulk substances that will be allowed by enforcement discretion and illegal compounding

Necessary and appropriate limits on this enforcement discretion are described in FDA's Draft Guidance for Industry #256. The guidance will enhance the safety of compounded drugs, ensuring confidence in the safety of the compounds.

Compounders who act like manufacturers have made several misleading and nonfactual claims about this guidance document—promoting these myths to Members of Congress. Here's a response to some of those myths:

MYTH: The guidance requires compounders to use finished drug products.

FACT: The guidance has no impact at all on compounding that is permitted by law under the Animal Medicinal Drug User Clarification Act (AMDUCA). The guidance only addresses illegal compounding from bulk substances.

Myth: The guidance only allows seven bulk drug substances to be used.

Fact: The Draft Guidance #256 proposes an initial list of seven bulk substances that can be used for animal drug compounding. But that list is not final. The guidance describes a process where bulk drug substances will be added to that list. In fact, FDA has established a process by which all stakeholders at any time can propose changes to the list.

MYTH: The cost of compounded medications would increase an average of 300%.

FACT: This guidance has no impact on legally compounded preparations under AMDUCA. They will not be impacted at all. Rather, veterinarians and animal owners risk higher costs of care when these deficient, untested products don't work. And in cases where the product is improperly made, large numbers of animals may and have experienced severe health consequences.

MYTH: The guidance will reduce the safety of compounded drugs.

FACT: In the past decade there have been documented instances of animals being killed or euthanized as a result of compounding errors. The guidance is specifically intended to increase the safety of compounded drugs given to animals and stop these tragic deaths. Compounded products are not proven to be safe and effective as are FDA-approved drugs. Finalizing the guidance is needed to increase safety.

MYTH: FDA lacks the statutory authority to issue this guidance.

FACT: The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA authority to oversee the safety of drugs. Compounding of animal drugs from bulk drug substances results in new animal drugs that must comply with the FD&C Act's approval/indexing requirements. This fact has been upheld by every Federal Court of Appeals that has considered the issue. This authority is clearly explained by FDA in Guidance #256.

A 2015 General Accountability Office report also acknowledges FDA's authority. One of the recommendations states FDA should "Develop policy or guidance for agency staff that specifies circumstances under which FDA will or will not enforce compounding regulations for animals and clearly define key terms." This is exactly what FDA has done in GFI #256. The guidance should immediately be finalized and enforced to protect animal health.

MYTH: There has not been sufficient opportunity for stakeholder input.

FACT: FDA published original guidance on this topic in 2015. After receiving input and comment that guidance was withdrawn. The current guidance was issued in 2019. After more than six years and two guidance documents, stakeholders have had ample time for input and now is the time for FDA to act.

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January 2022