Regulatory Brief

Invitation for AVMA to participate in FDA roundtable discussion on compounding pharmacies with medical stakeholders

The Food and Drug Administration (FDA) invited medical association stakeholders, including the AVMA, to participate in a dialogue regarding compounding pharmacies and the attending stakeholders’ engagement with the compounding industry.

Brief Description:
The Food and Drug Administration is working with Congress to consider new authorities over “non-traditional” compounding pharmacies following the fungal meningitis outbreak of 2012, which was a result of pharmaceuticals produced at the New England Compounding Company in Framingham, Massachusetts. The agency is engaging in dialogue with stakeholders, state representatives and Congressional offices as they determine the best way to provide oversight of the compounding industry.

AVMA Response:
Given the importance of compounding to the veterinary profession and treatment of animals, the AVMA appreciated the invitation to participate in the dialogue with the agency and medical colleagues. Veterinary medicine is unique in that a multitude of species with an even greater number of diseases and conditions need to be treated. The FDA’s approval of new animal drugs is critically important, as it would curtail the need for compounded preparations in veterinary medicine. At the same time, compounding is still necessary in some cases for veterinarians because there are, and always will be, a limited number of FDA-approved drugs for the many species and conditions that we treat. In addition, intermittent drug shortages and commercial unavailability of FDA-approved drugs drive the need for compounded preparations in various situations within veterinary medicine.

The term “compounding” comprises both compounding from FDA-approved drugs and from unapproved, bulk active pharmaceutical ingredients (API). Science-based evidence should be utilized to determine whether compounding a particular preparation should be done using a bulk API or an FDA-approved product with excipients. The AVMA believes it is medically necessary for veterinarians or pharmacists, under the direction of a veterinarian, to compound from bulk ingredients in limited circumstances:

- the approved drug is not commercially available, or
- the needed compounded preparation cannot be made from the approved drug.

The use of a compounded drug should be accompanied by the same precautions followed when using an approved drug, including counseling of the client regarding potential adverse reactions and attention to the potential for unintended human or animal exposure to the drug. The AVMA also firmly believes that the decision to use a compounded drug should be driven by the veterinarian within a Veterinarian-Client-Patient Relationship, not the pharmacist.
Effective regulatory mechanisms should be implemented to assure that compounding from bulk substances for animals is patient-specific and performed only in the context of a Veterinarian-Client-Patient Relationship. Strong, robust adverse event reporting systems could assist in the identification of problematic compounding situations and should also be implemented. The AVMA is opposed to egregious situations of manufacturing under the guise of compounding.

Background Documents:
- The AVMA response following the roundtable discussion (December 13, 2012). (PDF)
- FDA’s proposed Risk-based Framework
- AVMA’s Compounding webpage
- Relevant AVMA Policy
  - Compounding
  - Compounding from Unapproved (Bulk) Substances in Food Animals
  - Compounding from Unapproved (Bulk) Substances in Non-Food Animals