American Academy of Veterinary Pharmacology and Therapeutics
www.aavpt.org

November 9, 2015

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: **[Docket Nos. FDA-2015-D-1176 and FDA-2003-D-0202] Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry**

To Whom It May Concern:

The American Academy of Veterinary Pharmacology and Therapeutics (AAVPT) is an organization that promotes the science of veterinary pharmacology and therapeutics. AAVPT has over 350 members who are involved in academia, the animal health industry, and regulatory agencies, so our interest in compounding covers the gamut of considerations, including clinical use of compounded drugs, the study of benefits and risks of using compounded drugs, the regulation of compounded drugs, and the potential for inappropriate compounding represented by the copying of approved animal drugs. Our primary concerns about this draft guidance are the scientific aspects of drugs compounded from bulk, including:

1. Whether this Guidance adequately and clearly expresses the fact (and will result in clear and adequate education of veterinarians and animal owners) that drugs compounded from bulk are not the same as drugs used as labeled or drugs used in an extralabel manner. As such, we support the requirement to include on the prescription label the statement that the drug has been compounded and its safety, efficacy, and quality have not been evaluated.
2. Whether this Guidance will result in adequate enforcement of large scale compounding of bulk that is essentially manufacturing, with the concomitant lack of data on safety, efficacy, and chemical and manufacturing controls.
3. Whether the current system of capturing adverse events is amenable to and adequately configured and prepared to capture the adverse events associated with drugs compounded from bulk, and whether veterinarians and animal owners are adequately educated to understand that adverse events include lack of efficacy.
4. Whether any adverse event system created can appropriately attribute those events, including lack of effect, back to the correct product. If the pioneer drug is being used to compound but is not being used in the approved manner, how would that be reported, and could the manufacturer of the approved product be damaged? If active ingredient is

not from the approved product, will the reported adverse events then be attributed incorrectly to the approved product and manufacturer?

5. Whether this Guidance adequately defines how "clinical difference" should be evaluated and communicated, and how FDA intends to enforce the importance of this rationale for compounded drugs

The AAVPT contends that considerable education will be required to implement this Guidance, including for veterinarians, pharmacists, and the animal-owning public, to address the questions above as well as others expressed by other organizations.

Respectfully,

Ronette Gehring
President of the American Academy of Veterinary Pharmacology & Therapeutics