

November 16, 2015

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Subject: USP's Comments on Compounding Animal Drugs from Bulk Drug
Substances; Draft Guidance for Industry, Docket No. FDA-2015-D-1176

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the "Compounding Animal Drugs from Bulk Drug Substances Draft Guidance for Industry" (Draft Guidance). USP's standards for animal drugs support access to customized therapies designed for animal patients. We appreciate FDA's efforts in continuing to support standards for animal health, including recognizing the critical role of USP's compounding chapters. We look forward to working with FDA and other stakeholders on these important issues.

Similar to existing statutory and FDA requirements governing traditional compounding of human drug preparations, the Draft Guidance stipulates that licensed pharmacies and licensed veterinarians comply with [USP General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations and <797> Pharmaceutical Compounding—Sterile Preparations](#), and meet other conditions, if they want to compound animal drugs from bulk substances and be aligned with FDA's enforcement policy set forth in the Draft Guidance. USP fully supports this stipulation.

Related to FDA's intent to handle traditional animal compounding in this manner, the Agency has specifically requested comments on whether *United States Pharmacopeia and National Formulary (USP-NF) General Chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians.*

USP fully supports full compliance with both <795> and <797> when compounding extemporaneous preparations for animal patients as suitable standards.

I. USP Position

USP standards provide compounders with guidance on applying good compounding practices for extemporaneously compounded preparations. USP General Chapters <795> and <797> provide practice and quality standards for compounding preparations for human and animal patients. General Chapter <795> also provides specific information on compounding for animal patients. USP continues to encourage regulators to adopt USP General Chapters to help ensure the quality and benefit of compounded preparations for all patients. **USP's public standards on compounding protect animal patients—an important commitment to USP—and we are prepared to help ensure the utilization of General Chapters <795> and <797> as well as consider additional animal compounding-specific standards by working closely with FDA, States, practitioners, pharmacists, veterinarians, and other stakeholders.**

II. USP's Standards-Setting Role

USP is a scientific nonprofit organization that sets public standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements. USP develops its standards through Expert Committees, consisting of leading scientific expert volunteers, which are the ultimate decision-making bodies that approve USP standards, including monographs and general chapters. Consistent with our commitment to provide public standards, USP is advancing its animal health standards, including those devoted to veterinary drug products, whether in the form of a manufactured product or compounded preparation.

Animal-specific standards for drug substances and manufactured products are the responsibility of one of USP's six Chemical Medicines (CHM) Expert Committees, with support from two liaisons from the FDA Center for Veterinary Medicine (CVM). USP's compounding standards are developed through USP's Compounding Expert Committee, whose work is supported by eight FDA liaisons (including two from CVM) and two liaisons from the Centers for Disease Control (CDC). USP has been active in setting standards for animal drugs for many years including supporting the public's access to customized drug therapy for animal patients. For animal drug compounding, similar to human compounding, three types of standards add value by assuring quality for compounders, regulators, and animal patients:

1. [Monographs for drug articles](#)

Under the Federal Food, Drug, and Cosmetic Act, USP monographs for drug articles are legally enforceable by FDA. Monographs for drug articles include standards of identity, quality, purity, strength, packaging and labeling and are applicable to both human drugs and animal drugs. There are more than 190 veterinary-specific monographs for FDA approved drug substances and drug products.

2. [Veterinary-specific compounded preparation monographs](#)

There are currently more than 10 veterinary-specific compounded preparation monographs providing standardized formulas and beyond-use dates.

3. [General Chapters](#)

General Chapters may serve as introductory overviews of test or of analytical methods or provide more specific techniques or detailed procedures. In the case of <795> and <797>, they provide practice standards such as those for personnel and environments to ensure quality compounded preparations.

By way of information, General Chapters (in addition to <795> and <797>) relevant to Animal Drugs include:

- General Chapter <1151> *Pharmaceutical Dosage Forms* discusses general principles related to the manufacture or compounding of drug products, or dosage forms, commonly used to administer the drug substance (active pharmaceutical

ingredient, API) including general descriptions and definitions for these dosage forms.

- General Chapter <1152> Animal Drugs for Use in Animal Feeds provides important information and general principles involved in the manufacture, packaging, and labeling of animal drugs and drug products intended to be delivered in animal feeds.

We appreciate FDA's work in this area and look forward to continued collaboration with the Agency and other stakeholders.

Thank you for your consideration of this matter. For more information please feel free to contact Morgan Puderbaugh, Scientific Liaison, Science-Chemical Medicines, at (301) 998-6833 or mxp@usp.org; or Rick Schnatz, Pharm. D., Senior Manager, HQS and Compounding, Science-Healthcare Quality Standards, at (301) 816-8526 or rxs@usp.org.

Sincerely,



Jaap Venema, Ph.D.
Executive Vice President and Chief Science Officer