

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0290]

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**Compounding of Drugs for Use in Animals Compliance Policy Guide;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing the availability of a compliance policy guide (CPG) for FDA staff and industry entitled "Sec. 608.400 - Compounding of Drugs for Use in Animals," which provides guidance on how FDA intends to address compounding of animal drugs.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Director, Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or fax your request to 301-827-0482. Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Pl., rm. E441, Rockville, MD 20855, 301-827-0163, e-mail: nbatalle@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

On July 3, 1996, FDA issued a CPG section 608.400 “Compounding of Drugs for Use in Animals,” which provided guidance to FDA’s field and headquarters staff with regard to the compounding of drugs for use in animals by veterinarians and pharmacists. It described the factors FDA intended to consider in exercising its enforcement discretion regarding the illegal compounding of drugs intended for use in animals.

FDA is updating this CPG to ensure that its enforcement policy regarding the compounding of drugs intended for use in animals is consistent, to the extent practicable, with its enforcement policy regarding the compounding of drugs intended for use in humans. FDA issued the latter enforcement policy entitled “Pharmacy Compounding Compliance Policy Guide” that published in the **Federal Register** of June 7, 2002 (67 FR 39409). FDA issued this CPG after the U.S. Supreme Court ruled that a statutory provision governing the compounding of drugs intended for human use was unconstitutional. Because of that court decision, FDA determined that it needed to issue guidance to the compounding industry on what types of compounding might be subject to enforcement action under current law. The guidance was based in part on an earlier CPG.

In addition to ensuring that its policies regarding the compounding of drugs intended for use in humans and animals are consistent, FDA is revising its previous animal drug compounding CPG to ensure it is consistent with the current animal drug compounding regulations, which are codified at 21 CFR part 530.

II. Significance of Guidance

This compliance policy guidance is being issued as a level 1 guidance consistent with FDA's good guidance practices (GGPs) regulation in § 10.115 (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because of the agency's urgent need to explain how, in light of the recent court decision and revised policy regarding drugs for human use, it intends to exercise its enforcement discretion regarding compounded drugs for animal use. However, under GGPs, FDA requests comments on the guidance and will revise the document, if appropriate. Comments will be considered by the agency in the development of future policy.

This compliance policy guidance represents the agency's current thinking on the enforcement of the act with regard to drug products compounded for use in animals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

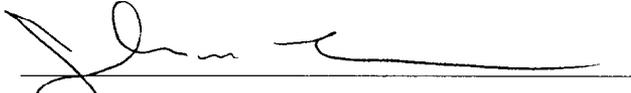
III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the CPG at any time. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain copies of the CPG at FDA's Office of Regulatory Affairs Web site at <http://www.fda.gov/ora> under "Compliance References."

Dated: 7/8/03
July 8, 2003.



John M. Taylor,
Associate Commissioner for Regulatory Affairs.

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