

Sec. 608.200 Prescription Use of Certain Injectable Animal Drugs

Compliance Policy Guide

Guidance for FDA Staff

*This version of the Compliance Policy Guide replaces the version made available March 1995.
This revision of the CPG makes formatting changes and minor editorial changes for
clarification.*

Additional copies are available from:
Policy and Regulations Staff (HFV-6)
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

<https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm>

Submit either electronic or written comments on this compliance policy guide (CPG) at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-2018-N-3338.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
and
Center for Veterinary Medicine**

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This compliance policy guide represents the current thinking of the Food and Drug Administration (FDA) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this compliance policy guide as listed on the title page.

I. Introduction

The purpose of this compliance policy guide (CPG) is to provide guidance for FDA staff on prescription legend requirements for certain injectable animal drugs.

In general, FDA's guidance documents, including this CPG, do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on various topics and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Section 503(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and title 21, Code of Federal Regulations § 201.105 (21 CFR 201.105), set forth the conditions for prescription legend requirements for animal drugs. These include such factors as the toxicity or other potentiality for harmful effect, or the method of use which necessitates the supervision of a licensed veterinarian for safe use. Adequate directions for safe use of such drugs by laypersons cannot be written. Section 503(f)(4) of the FD&C Act recites the veterinary legend caution statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." Other terms such as "for veterinary use only" and "for sale to graduate veterinarians" are not the prescription legend.

There are some animal injectable drugs which cannot be safely used except under the supervision of a licensed veterinarian. These include the following:

- a. All drugs labeled for intravenous (IV) administration in dogs, cats, and other small animals;
- b. All drugs labeled for intra-articular, intrathecal, epidural, paravertebral, subconjunctival, and retrobulbar administration in all species;

Contains Nonbinding Recommendations

- c. All drugs labeled for intraperitoneal administration in horses.

III. Policy

Those animal drugs in a., b., and c. above are in violation of section 502(f)(1) of the FD&C Act unless they bear the prescription legend statement.

IV. Regulatory Action Guidance

If any of the above dosage forms listed in a., b., or c. are marketed without the veterinary prescription legend, they bear inadequate directions for use and are in violation of section 502(f)(1) of the FD&C Act. For follow up regulatory action, contact the CVM Division of Compliance, Post-Market Compliance Team (HFV-232) at 240-402-7001, or email: AskCVM@fda.hhs.gov.

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