

Sec. 665.300 Use of Type A Medicated Article Proprietary Names in the Names of Medicated Feeds

Compliance Policy Guide

Guidance for FDA Staff

This version of the Compliance Policy Guide replaces the version made available June 1986. The document has been revised to current CPG formatting standards, update contact information, and clarify existing language.

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-3189.

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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Contains Nonbinding Recommendations

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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 it 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 the inclusion of proprietary names (i.e., brand or trade name) of Type A medicated articles in the names of medicated feeds.

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

In this CPG, the term proprietary name refers to the trademark or brand name of a drug product. The proprietary name is the exclusive name of a drug product owned by a company under trademark law regardless of registration status with the United States Patent and Trademark Office. To identify the source of the new animal drug used in a medicated feed, a medicated feed manufacturer may choose to include the proprietary name of the Type A medicated article in the name of the medicated feed manufactured from the Type A medicated article.

III. Policy

When the Type A medicated article proprietary name is included in the name of the medicated feed, the medicated feed labeling should include the name of the active ingredient(s), i.e., drug product. The proprietary name may only be used in the product name in a manner which is not misleading in any particular. To minimize the potential for confusion, the numerical part of the proprietary name, if any, should not be included in the

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name of the medicated feed because a numerical part of a Type A medicated article's proprietary name could be interpreted as a drug concentration in the feed.

The proprietary name of the Type A medicated article is confined to the use in the name of the medicated feed and should not be used in place of the required label statement of active ingredients or in any other listing of ingredients or in any statement of guaranteed analysis. Any other use of the Type A medicated article proprietary name elsewhere on the labeling must adhere to the use on the applicable representative (i.e., Blue Bird) label for the feed (see the Federal Food, Drug, and Cosmetic Act, section 512(a)(1)(A) (21 U.S.C. 360b(a)(1)(A))).

This policy is consistent with the Model Regulations under the Model Bill, and the labeling guidelines adopted by the Association of American Feed Control Officials (AAFCO), as set forth in their Official Publication and enacted into law by most states.

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