

Sec. 666.100 Alternate Feeding of Different Medicated Feeds

Compliance Policy Guide

Guidance for FDA Staff

This version of the Compliance Policy Guide replaces the version made available July 1981. The document has been revised to current CPG formatting standards, to update contact information, and to 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-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 the practice of alternate feeding of different medicated feeds. In this document the term “alternate feeding” includes any separate feeding of different medicated feeds to the same animals in the same day as well as concurrent feeding of different 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

Feedlots and other animal producers sometimes consider adopting the practice of alternately feeding different medicated feeds, both containing drugs which, if combined in a single feed, would require an approved new animal drug application. One example of such an alternate feeding practice is feeding one medicated feed in the morning and another medicated feed in the afternoon of the same day, which is often referred to as “AM-PM feeding.” Another example of an alternate feeding practice includes concurrent feeding of different medicated feeds during the same feeding. These practices bring into question drug safety and effectiveness.

III. Policy

The FDA does not accept the practice of alternate feeding of different medicated feeds. This practice could result in above tolerance tissue residues, and if so, is a violation of section 501(a)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Alternate feeding of different medicated feeds would expose the animals to unapproved drug combinations by enabling separately approved and fed drugs to get mixed in the animals’ digestive tracts. Such practice also would violate 21 CFR 514.4(c), which requires substantial evidence for combination new animal drugs. If an animal producer holding an approved medicated feed mill license practices alternate feeding, a violation of section 512(m)(4) of the FD&C Act occurs and

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subjects the approved medicated feed mill license to consideration of revocation proceedings if voluntary correction cannot be obtained.

The FDA would not consider the one-time switch necessary to take the animals from one medicated feed to another as alternate feeding, even if the previous medicated feed was fed, for example, in the morning, and the subsequent medicated feed was fed in the afternoon of the same day.

Also, the FDA would not consider feeding performed according to a regulation as alternate feeding. For example, due to the manner in which melengestrol acetate was approved (see 21 CFR 558.342), feeding the entire approved daily amount of the drug melengestrol acetate in one feeding, but not in other feedings that day, would not be considered alternate feeding.

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