Compliance Policy Guides

Compliance Policy Guidance for FDA Staff

Sec. 615.115

Extra-Label Use of Medicated Feeds for Minor Species

Department of Health and Human Services

Food and Drug Administration

Office of Enforcement

Division of Compliance Policy

MARCH 2001

COMPLIANCE POLICY GUIDE
CHAPTER – 6
SUBCHAPTER – 615

Sec. 615.115 Extra-label Use of Medicated Feeds for Minor Species

INTRODUCTION

This compliance guidance document (Compliance Policy Guide) is an update to the Compliance Policy Guides Manual (August 1996 edition). It is a new Compliance Policy Guide and will be included in the next printing of the Compliance Policy Guides Manual. It is intended for FDA personnel and is available electronically to the public. It represents the Agency's current thinking on extra-label use of medicated feeds for minor species (as defined in 21 CFR 514.1 (d)(1)(ii)). Minor species are defined by exclusion as animals other than cattle, horses, swine, chickens, turkeys, dogs and cats. The document is intended to provide guidance to the field concerning the Agency's exercise of regulatory discretion with regard to the extra-label use of medicated feeds for minor species. It does not confer any rights for or on any person and does not operate to bind FDA or the public.

BACKGROUND

Prior to 1994, the Federal Food, Drug, and Cosmetic Act (the Act) did not permit the extra-label use of animal drugs, but the Agency exercised regulatory discretion regarding extra-label use of animal drugs provided certain criteria were met. These criteria were published in Compliance Policy Guide 7125.06 and were largely incorporated into the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). AMDUCA amended the Act to permit extra-label uses under certain conditions. The regulations promulgated pursuant to AMDUCA are codified at 21 CFR part 530.

AMDUCA did not permit extra-label use of medicated feeds. However, there are some minor species that cannot be practically medicated in any way other than through the use of medicated feeds. Furthermore, minor species such as fish and game birds have very few drugs approved for their use. In such situations, a veterinarian may determine that extra-label use of medicated feeds approved for use in other species can prevent suffering and death in these minor species.

Before the implementation of AMDUCA, the Agency occasionally exercised regulatory discretion for extra-label use of medicated feeds for minor species based on a medical need as long as the medicated feeds were formulated and labeled in accordance with

their approved application. Because AMDUCA did not permit extra-label use of medicated feeds, the Agency is providing this guidance to our field personnel for use when such extra-label use is encountered.

POLICY

The use or intended use of medicated feeds for treating animals in any manner other than in accordance with the approved labeling causes the drug used in the feed to be adulterated within the meaning of Section 501(a)(5) of the Act and the medicated feed to be adulterated within the meaning of Section 501(a)(6) of the Act. The Agency will consider regulatory action when it finds such use or intended use.

Nevertheless, extra-label use of medicated feed for treatment of minor species may be considered when the health of animals is threatened and suffering or death would result from failure to treat the affected animals. In instances of this nature, the Agency will not ordinarily consider regulatory action against the veterinarian or animal producer provided all of the circumstances listed below exist.

Similarly, the Agency is unlikely to take regulatory action against a feed mill in instances where it produces a properly formulated and labeled medicated feed even though the feed mill may be aware that such feed is intended to be used for an extra-label purpose for minor species. This also presumes that those circumstances listed below that are applicable to feed mills exist. The Agency anticipates that any regulatory action taken based on the extra-label use of a medicated feed for a minor species will be directed at the following:

1. veterinarians who authorize such use in a manner that is inconsistent with this guidance;

2. animal producers who use the feed in a manner that is inconsistent with this guidance;

3. all persons, including veterinarians and animal producers, who promote the feed for extra-label use; and

4. feed mills that manufacture/ distribute the feed in disregard of this guidance.

Under this guidance, the Agency ordinarily will not consider regulatory action if:

1. The medicated feed is used in an extra-label manner only for treatment of minor species as defined in the Code of Federal Regulations (21 CFR 514.1 (d)(1)(ii)). For the purposes of this guidance, "extra-label use" refers to the actual or intended use of an approved medicated feed in a manner that is not in accordance with the approved labeling. Extra-label use includes, but is not limited to:

    - use in minor species not listed in the labeling,
    - use for indications (diseases or other conditions) not listed in the labeling, and
    - deviation from the labeled withdrawal time;

2. The medicated feed is approved for use in a major species animal and is formulated and labeled according to its approved labeling as described in the Code of Federal Regulations (21 CFR part 558). The nutrient content and formulation are in accordance with use in the approved major species. The labeling reflects the approved use in dosage, formulation, and nutrient content;

3. The medicated feed is to be used in a food-producing minor species and the feed is approved in a major food-producing species;

4. Extra-label use of medicated feed in aquaculture is limited to medicated feed products approved for use in aquatic species;

5. Extra-label use of medicated feed is limited to farmed or confined minor species. Use for the treatment of unconfined wildlife is not appropriate under this policy;

6. The medicated feed is used in an extra-label manner only with the express prior written recommendation (see part 8.h. of this guidance) and oversight of an attending licensed veterinarian within the context of a valid veterinarian-client-patient relationship. A valid veterinarian-client-patient relationship is defined as one in which:

   a. a veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (the owner or other caretaker of the animal(s)) has agreed to follow the instructions of the veterinarian;

   b. the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept;

   c. there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

   d. the veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy;

7. Extra-label use is limited to therapeutic treatments when the health of an animal is threatened and suffering or death may result from failure to treat. It is inappropriate under any circumstances to use a medicated feed in an extra-label manner for improving rate of weight gain, feed efficiency, or other production purposes;

8. The veterinarian has:

   a. made a careful diagnosis and evaluation of the conditions for which the drug is to be used;

   b. made a determination that there is no approved new animal drug that (i) is labeled for such use, and (ii) contains the same active ingredient which is in the dosage form and concentration necessary for treatment;

   c. made a determination, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug, if any, is clinically ineffective for its intended use;

   d. ascertained that there is no therapeutic dosage form that can be practically used under legal extra-label use;

   e. established a withdrawal period that is substantially extended beyond that of the approved use (supported by appropriate scientific information) prior to marketing of milk, meat, eggs, or other edible products derived from the treated minor species, if applicable;

   f. instituted procedures to assure that the identity of treated animals is carefully maintained;

   g. taken appropriate measures to

assure that assigned timeframes for withdrawal are met and no unsafe drug residues occur in any food-producing animal subjected to extra-label treatment;

h. made a written recommendation that includes the medical rationale (e.g., diagnosis, drug selection, dose and duration, and the required withdrawal period), dated within 3 months prior to use. The animal producer and the veterinarian have kept copies and make them available to the FDA upon request; and

i. Has reported any adverse reactions to FDA within 10 days of occurrence (1-888-FDA-VETS).

9. The animal producer has:

a. kept complete and accurate records of feeds received, including labels, invoices, and dates fed. These records are kept for at least 1 year from the date of delivery;

b. kept a current copy of the veterinarian's written recommendation for the extra-label use of the medicated feed;

c. instituted procedures to assure that the identity of treated animals is carefully maintained;

d. taken appropriate measures to assure that assigned timeframes for withdrawal are met and no unsafe drug residues occur in any food-producing animal subjected to extra-label treatment;

e. used the medicated feed in accordance with federal, state, and local environmental and occupational laws and regulations. This is especially important for aquaculture uses;

f. met the requirements of the federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES), as well as any requirements applicable to ground-water pollution. The producer should contact the offices responsible for issuing NPDES permits, and other similar permits, to be certain they have no objection to the use and release of the drug; and

g. followed user safety provisions as set forth in approved product labeling to protect individuals who may be exposed to the drug.

REGULATORY GUIDANCE

In instances where the above circumstances do not exist, the following regulatory steps may be taken. A Warning Letter is ordinarily the first choice of action. The following language should be used to cite the violation:

> The animal drug **** is adulterated within the meaning of Section 501(a)(5) as its use or intended use does not conform to its approved application in accordance with Section 512(a)(1)(B).
>
> The animal feed **** is adulterated within the meaning of Section 501(a)(6) as its use or intended use does not conform to its approved application in accordance with Section 512(a)(2)(C).

If a veterinarian did not recommend the use

of the feed for extra-label purposes, the Warning Letter should be issued to the animal producer with a copy sent to the veterinarian, if any. If a veterinarian recommended the use of the feed for extra-label use other than as described above, the Warning Letter should be issued to the veterinarian with a copy sent to the animal producer.

If the feed is not formulated and labeled in accordance with approved conditions of use as described in the Code of Federal Regulations, a Warning Letter should be issued to the feed mill, with a copy to the animal producer or veterinarian, if any.

The feed mill also may be considered for regulatory action if there is sufficient evidence to show that it knew that the feed was intended for extra-label use in other than a minor species.

If there is a tissue residue violation, the District should establish the responsible individuals. This would ordinarily be the animal producer and/or veterinarian if not covered under the circumstances of this policy. However, in rare situations such as documented misformulation or no approval in 21 CFR part 558, the feed mill may be considered responsible for the violation.

The following language should be used to cite the tissue residue violation:

> A (type of animal) sold for food on or about (date) is adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Food, Drug and Cosmetic Act. Analysis of tissues disclosed the presence of the drug (level and name of drug for each tissue in which illegal residue was reported.) There is no tolerance for this drug in the edible tissues of (type of animal). Our investigation revealed that you are responsible for this violation.

Should field personnel have any questions about the application of this guidance, they may call CVM's Division of Compliance, Drugs and Device Team at (301) 827-0150.

Issued: DATE