

**PART 558—NEW ANIMAL DRUGS
FOR USE IN ANIMAL FEEDS**

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Subpart A—General Provisions

§ 558.3 Definitions and general considerations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved or are regulated on a “no-residue” basis or with a “zero” tolerance because of a carcinogenic concern regardless whether a withdrawal period is required.

(2) A “Type A medicated article” is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g.,

calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under §514.105(a) of this chapter.

(3) A "Type B medicated feed" is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term "highest continuous use level" means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category II, Type A medicated article requires an application approved under §514.105(b) of this chapter.

(4) A "Type C medicated feed" is intended as the complete feed for the animal or may be fed "top dressed" (added on top of usual ration) on or offered "free-choice" (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nu-

trients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Category II, Type A medicated article requires an application approved under §514.105(b) of this chapter.

(5) A Type B or Type C medicated feed manufactured from a drug component (bulk or "drum-run" (dried crude fermentation product)) requires an application approved under §514.105(a) of this chapter.

[51 FR 7392, Mar. 3, 1986, as amended at 52 FR 2682, Jan. 26, 1987; 54 FR 51386, Dec. 15, 1989; 56 FR 19268, Apr. 26, 1991]

§558.4 Medicated feed applications.

(a) The manufacture of a Type B or Type C medicated feed from a Category I, Type A medicated article is exempt from the requirement of an approved medicated feed application.

(b) The manufacture of a Type B or Type C medicated feed from a Category II, Type A medicated article requires an approved medicated feed application.

(c) The use of Type B and Type C medicated feeds shall conform to the conditions of use provided for in subpart B of this part and in §§510.515 and 558.15.

(d) This paragraph identifies each drug by category, the maximum level of drug in Type B medicated feeds, and the assay limits for the drug in Type A medicated articles and Type B and Type C medicated feeds, as follows:

CATEGORY I

Drug	Assay limits percent ¹ type A	Type B maximum (200x)	Assay limits percent ¹ type B/C ²
Aklomide	90-110	22.75 g/lb (5.0%)	85-120.
Amprolium with Ethopabate	94-114	22.75 g/lb (5.0%)	80-120.
Bacitracin methylene disalicylate	85-115	25.0 g/lb (5.5%)	70-130.
Bacitracin zinc	84-115	5.0 g/lb (1.1%)	70-130.
Bambermycins	90-110	800 g/ton (0.09%)	80-120/70-130.
Buquinolate	90-110	9.8 g/lb (2.2%)	80-120.
Chlortetracycline	85-115	40.0 g/lb (8.8%)	80-115/70-130.
Coumaphos	95-115	6.0 g/lb (1.3%)	80-120.
Decoquinatate	90-105	2.72 g/lb (0.6%)	80-120.
Dichlorvos	100-115	33.0 g/lb (7.3%)	90-120/80-130.
Efrotomycin	94-113	1.45 g/lb (0.32%)	80-120
Erythromycin (thiocyanate salt)	85-115	9.25 g/lb (2.04%)	<20g/ton 70-115/150-50;>20g/ton 75-125.