

#### § 558.4

#### 21 CFR Ch. I (4–1–14 Edition)

contains a substantial quantity of nutrients 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 a medicated feed mill license application approved under § 515.20 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 of this chapter or an index listing granted under § 516.151 of this chapter.

(6) A “veterinary feed directive (VFD) drug” is a new animal drug approved under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) or listed in the index under section 572 of the act for use in or on animal feed. Use of a VFD drug must be under the professional supervision of a licensed veterinarian.

(7) A “veterinary feed directive” is a written statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client’s animals only in accordance with the directions for use approved or indexed by the Food and Drug Administration (FDA). A veterinarian may issue a VFD only if a valid veterinarian-client-patient relationship exists, as defined in § 530.3(i) of this chapter.

(8) A “medicated feed” means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

(9) For the purposes of this part, a “distributor” means any person who distributes a medicated feed containing

a VFD drug to another distributor or to the client-recipient of the VFD.

(10) An “animal production facility” is a location where animals are raised for any purpose, but does not include the specific location where medicated feed is made.

(11) An “acknowledgment letter” is a written communication provided to a distributor by a consignee who is not the ultimate user of medicated feed containing a VFD drug. An acknowledgment letter affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another distributor without receiving a similar written acknowledgment letter.

[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; 64 FR 63206, Nov. 19, 1999; 65 FR 76929, Dec. 8, 2000; 72 FR 69130, Dec. 6, 2007]

#### § 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

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

(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 <sup>1</sup> type A	Type B maximum (200x)	Assay limits percent <sup>1</sup> type B/C <sup>2</sup>
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.
Chlortetracycline .....	85-115	40.0 g/lb (8.8%) .....	80-115/70-130.
Coumaphos .....	95-115	6.0 g/lb (1.3%) .....	80-120.
Decoquinat .....	90-105	2.72 g/lb (0.6%) .....	80-120.
Dichlorvos .....	100-115	33.0 g/lb (7.3%) .....	90-120/80-130.
Diclazuril .....	90-110	182 g/t (0.02%) .....	85-115/70-120.
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.
Iodinated casein .....	85-115	20.0 g/lb (4.4%) .....	75-125.
Laidlomycin propionate potassium .....	90-110	1 g/lb (0.22%) .....	90-115/85-115.
Lasalocid .....	95-115	40.0 g/lb (8.8%) .....	Type B (cattle and sheep): 80-120; Type C (all): 75-125.
Lincomycin .....	90-115	20.0 g/lb (4.4%) .....	80-130.
Melengestrol acetate .....	90-110	10.0 g/ton (0.0011%) .....	70-120.
Monensin .....	85-115	40.0 g/lb (8.8%) .....	Chickens, turkeys, and quail: 75-125; Cattle: 5-10 g/ton 80-120; Cattle: 10-30 g/ton 85-115; Goats: 20 g/ton 85-115; Liq. feed: 80-120.
Narasin .....	90-110	7.2 g/lb (1.6%) .....	85-115/75-125.
Nequinat .....	95-112	1.83 g/lb (0.4%) .....	80-120.
Niclosamide .....	85-120	225g/lb (49.5%) .....	80-120.
Nystatin .....	85-125	5.0 g/lb (1.1%) .....	75-125.
Oleandomycin .....	85-120	1.125 g/lb (0.25%) .....	<11.25 g/ton 70-130; >11.25 g/ton 75-125.
Oxytetracycline .....	90-120	20.0 g/lb (4.4%) .....	75-125/65-135.
Penicillin .....	80-120	10.0 g/lb (2.2%) .....	65-135.
Poloxalene .....	90-110	54.48 g/lb (12.0%) .....	Liq. feed: 85-115.
Ractopamine .....	85-105	2.46 g/lb (0.54%) .....	80-110/75-125.
Salinomycin .....	95-115	6.0 g/lb (1.3%) .....	80-120.
Semduramicin (as semduramicin sodium).	90-110	2.27 g/lb (0.50%) .....	80-110
Semduramicin (as semduramicin sodium biomass).	90-110	2.27 g/lb (0.50%) .....	80-120
Tylosin .....	80-120	10.0 g/lb (2.2%) .....	75-125.
Virginiamycin .....	85-115	10.0 g/lb (2.2%) .....	70-130.
Zoalene .....	92-104	11.35 g/lb (2.5%) .....	85-115.

<sup>1</sup> Percent of labeled amount.

<sup>2</sup> Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

CATEGORY II

Drug	Assay limits percent <sup>1</sup> Type A	Type B maximum (100x)	Assay limits percent <sup>1</sup> Type B/C <sup>2</sup>
Amprolium .....	94-114	11.35 g/lb (2.5%) .....	80-120.
Apramycin .....	88-112	7.5 g/lb (1.65%) .....	80-120.
Carbadox .....	90-110	2.5 g/lb (0.55%) .....	75-125.
Clopidol .....	94-106	11.4 g/lb (2.5%) .....	90-115/80-120.
Famphur .....	100-110	5.5 g/lb (1.21%) .....	90-115/80-120.
Fenbendazole .....	93-113	8.87 g/lb (1.96%) .....	75-125
Florfenicol .....	90-110	9.1 g/lb (2.0%) .....	Swine feed: 85-115 Catfish feed: 80-110 Salmonid feed: 80-110
Halofuginone hydrobromide .....	90-115	272.0 g/ton (.03%) .....	75-125.
Hygromycin B .....	90-110	1,200 g/ton (0.13%) .....	75-125.
Ivermectin .....	95-105	1,180 g/ton (0.13%) .....	80-110.
Maduramicin ammonium .....	90-110	545 g/ton (.06%) .....	80-120.
Morantel tartrate .....	90-110	66.0 g/lb (14.52%) .....	85-115.
Neomycin .....	80-120	7.0 g/lb (1.54%) .....	70-125.
Oxytetracycline .....	80-120	10.0 g/lb (2.2%) .....	65-135.
Neomycin sulfate .....	80-120	100 g/lb (22.0%) .....	70-125.
Nicarbazin (granular) .....	90-110	5.675 g/lb (1.25%) .....	85-115/75-125

CATEGORY II—Continued

Drug	Assay limits percent <sup>1</sup> Type A	Type B maximum (100x)	Assay limits percent <sup>1</sup> Type B/C <sup>2</sup>
Narasin	90-110	5.675 g/lb (1.25%)	85-115/75-125
Nicarbazin (powder)	98-106	5.675 g/lb (1.25%)	85-115/80-120
Nitarsonic	90-110	8.5 g/lb (1.87%)	85-120.
Novobiocin	85-115	17.5 g/lb (3.85%)	80-120.
Pyrantel tartrate	90-110	36 g/lb (7.9%)	75-125.
Robenidine	95-115	1.5 g/lb (0.33%)	80-120.
Ronnel	85-115	27.2 g/lb (6.0%)	80-120.
Sulfadimethoxine	90-110	5.675 g/lb (1.25%)	85-115/75-125.
Ormetoprim (5/3)	90-110	3.405 g/lb (0.75%)	85-115.
Ormetoprim (5/1)	90-110	17.0 g/lb (3.75%)	85-115.
Sulfaethoxypyridazine	95-105	50.0 g/lb (11.0%)	85-115.
Sulfamerazine	85-115	18.6 g/lb (4.0%)	85-115.
Sulfamethazine	85-115	10.0 g/lb (2.2%)	80-120.
Chlortetracycline	85-115	10.0 g/lb (2.2%)	85-125/70-130.
Penicillin	85-115	5.0 g/lb (1.1%)	85-125/70-130.
Sulfamethazine	85-115	10.0 g/lb (2.2%)	80-120.
Chlortetracycline	85-115	10.0 g/lb (2.2%)	85-125/70-130.
Sulfamethazine	85-115	10.0 g/lb (2.2%)	80-120.
Tylosin	80-120	10.0 g/lb (2.2%)	75-125.
Sulfaquinoxaline	98-106	11.2 g/lb (2.5%)	85-115.
Thiabendazole	94-106	45.4 g/lb (10.0%)	>7% 85-115; <7% 90-110.
Tiamulin hydrogen fumarate	90-115	10 g/lb	90-115/70-130
Tilmicosin	90-110	37.9 g/lb (8.35%)	85-115.
Zilpaterol	90-110	680 g/t (0.075%)	80-110/75-115

<sup>1</sup> Percent of labeled amount.

<sup>2</sup> Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

(e) When drugs from both categories are in combination, the Category II requirements will apply to the combination drug product.

[51 FR 7392, Mar. 3, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).

**§ 558.5 Requirements for liquid medicated feed.**

(a) *What types of liquid medicated feeds are covered by this section?* This section covers the following types of liquid medicated feed:

- (1) Type B feed that is intended for further manufacture of other medicated feeds (§ 558.3(b)(3)) or:
- (2) Type C feed that is intended for the following:
  - (i) Further manufacture of another Type C feed, or
  - (ii) Top-dressing (adding on top of the usual ration) (§ 558.3(b)(4)).
- (b) *How is liquid free-choice medicated feed regulated?* Liquid free-choice medi-

cated feed is covered by this section and by § 510.455.

(c) *What is required for new animal drugs intended for use in liquid feed?* Any new animal drug intended for use in liquid feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) or index listed under section 572 of the act. Such approvals under section 512 of the act must be:

- (1) An original NADA,
- (2) A supplemental NADA, or
- (3) An abbreviated NADA.

(d) *What are the approval requirements under section 512 of the act for new animal drugs intended for use in liquid feed?* An approval under section 512 of the act for a new animal drug intended for use in liquid feed must contain the following information:

- (1) Data, or a reference to data in a master file (MF), that shows the relevant ranges of conditions under which the drug will be chemically stable in liquid feed under field use conditions; and