

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 a medicated feed mill license application approved under § 515.20 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 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.

(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) 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 veterinary feed directive (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 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]

#### § 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 §§ 510.515 and 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>
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.
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.
Nequinatate .....	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	1.8 g/lb (0.4%) .....	80–110/75–125.
Salinomycin .....	95–115	6.0 g/lb (1.3%) .....	80–120.
Semduramicin .....	90–110	2.25 g/lb (0.50%) .....	80–110.
Tiamulin .....	113.4 g/lb, 100–108 5 and 10 g/1b, 90–115	3.5 g/lb (0.8%) .....	90–115.
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.
Arsanilate sodium .....	90–110	4.5 g/lb (1.0%) .....	85–115/75–125.
Arsanilic acid .....	90–110	4.5 g/lb (1.0%) .....	85–115/75–125.
Carbadox .....	90–110	2.5 g/lb (0.55%) .....	75–125.
Carbarsone .....	93–102	17.0 g/lb (3.74%) .....	85–115.
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.

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>
Fenbendazole	93–113	8.87 g/lb (1.96%)	75–125
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.
Levamisole	85–120	113.5 g/lb (25%)	85–125.
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
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
Nitarosone	90–110	8.5 g/lb (1.87%)	85–120.
Nitromide	90–110	11.35 g/lb (2.5%)	80–120.
Sulfantran	85–115	13.6 g/lb (3.0%)	75–125.
Nitromide	90–110	11.35 g/lb (2.5%)	85–115.
Sulfantran	85–115	5.65 g/lb (1.24%)	75–125.
Roxarsone	90–110	2.275 g/lb (0.5%)	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.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Aklomide	90–110	11.35 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Clopidol	94–106	11.35 g/lb (2.5%)	80–120.
Bacitracin methylene disalicylate	85–115	5.0 g/lb (1.1%)	70–130.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Monensin	90–110	5.5 g/lb (1.2%)	75–125.
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.
Sulfadimethoxine	90–110	85.1 g/lb (18.75%)	85–115/75–125.
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.
Sulfantran	85–115	13.6 g/lb (3.0%)	75–125.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Sulfantran	85–115	13.6 g/lb (3.0%)	75–125.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.715 g/lb (0.60%)	85–120.
Sulfantran	85–115	13.6 g/lb (3.0%)	75–125.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.27 g/lb (0.5%)	85–120.
Sulfaquinoxaline	98–106	11.2 g/lb (2.5%)	85–115.
Sulfathiazole	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–125	10.0g/lb (2.2%)	70–130.
Penicillin	80–120	5.0 g/lb (1.1%)	70–130.
Thiabendazole	94–106	45.4 g/lb (10.0%)	>7% 85–115; <7% 90–110.
Tilmicosin	90–110	18.2 g/lb (4.0%)	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 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.

## § 558.5

(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 on GPO Access.

### § 558.5 New animal drug requirements for liquid Type B feeds.

(a) Information available to the Commissioner of Food and Drugs shows that certain drugs are unstable when added to some liquid Type B medicated feeds. The demonstrated instability of these drugs gives rise to the question of the stability of other drugs when added to liquid Type B medicated feeds, except where specific approval has been granted for such use. Therefore, the labeling of a drug to provide for its use in a liquid Type B medicated feed causes the drug to be a new animal drug for such use for which an approved new animal drug application is required pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act.

(b) The addition of a drug to a liquid Type B medicated feed causes such Type B feed to become an animal feed bearing or containing a new animal drug for which an approved application is required pursuant to section 512(m) of the act.

(c) Each drug product, intended for oral administration to animals, which contains any of the drugs listed in paragraph (d) of this section and which bears labeling for its use in animal feed and/or drinking water shall also include in such labeling the following statement: "FOR USE IN \_\_\_\_\_ ONLY. NOT FOR USE IN LIQUID TYPE B MEDICATED FEEDS," the blank being filled in with the words "DRY FEEDS," "DRINKING WATER," "DRY FEEDS AND DRINKING WATER" as applicable, unless:

(1) Such drug product is the subject of an approved new animal drug application providing for its use in liquid Type B medicated feeds, or;

(2) The labeling provisions of this paragraph have been waived on the basis of approval of a petition which in-

## 21 CFR Ch. I (4-1-03 Edition)

cludes a copy of the product label; a description of the formulation; and information which establishes that the physical, chemical, or other properties of the particular drug product are such that it cannot reasonably be expected to be diverted for use in liquid Type B medicated feeds. Such petitions shall be submitted to the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(d) The labeling provisions of paragraph (c) of this section apply to all forms of bacitracin, oxytetracycline, and chlortetracycline.

(e) For any drug which is the subject of an approved new animal drug application, the labeling provisions of paragraph (c) of this section may be implemented without prior approval as provided for in § 514.8(d) and (e) of this chapter.

[40 FR 13959, Mar. 27, 1975, as amended at 52 FR 2684, Jan. 26, 1987; 57 FR 6475, Feb. 25, 1992]

### § 558.6 Veterinary feed directive drugs.

(a) What conditions must I meet if I am a veterinarian issuing a veterinary feed directive (VFD)?

(1) You must be appropriately licensed.

(2) You must issue a VFD only within the confines of a valid veterinarian-client-patient relationship (see definition at § 530.3(i) of this chapter).

(3) You must complete the VFD in writing and sign it or it will be invalid.

(4) You must include all of the following information in the VFD or it will be invalid:

(i) You and your client's name, address and telephone and, if the VFD is faxed, facsimile number.

(ii) Identification and number of animals to be treated/fed the medicated feed, including identification of the species of animals, and the location of the animals.

(iii) Date of treatment, and, if different, date of prescribing the VFD drug.

(iv) Approved indications for use.

(v) Name of the animal drug.

(vi) Level of animal drug in the feed, and the amount of feed required to