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 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 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 [1] type A	Type B maximum (200x)	Assay limits percent [1] type B/C [2]
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.
Decoquinate	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.
Nequinate	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.

[1] Percent of labeled amount.

[2] 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 [1] Type A	Type B maximum (100x)	Assay limits percent [1] Type B/C [2]
Amprolium	94–114	11.35 g/lb (2.5%)	80–120.
Apramycin	88–112	7.5 g/lb (1.65%)	80–120.
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.

CATEGORY II—Continued

Drug	Assay limits percent [1] Type A	Type B maximum (100x)	Assay limits percent [1] Type B/C [2]
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
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
Nitarsone	90–110	8.5 g/lb (1.87%)	85–120.
Sulfanitran	85–115	13.6 g/lb (3.0%)	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.
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.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.715 g/lb (0.60%)	85–120.
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.
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

[1] Percent of labeled amount.

[2] 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*.

§ 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 medicated 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

(2) Data, or a reference to data in an MF, that shows that the drug is physically stable in liquid feed under field conditions; or

(3) Feed labeling with recirculation or agitation directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *How are chemical and physical stability data to be submitted?* The data must be submitted as follows:

(1) Directly in the NADA,

(2) By a sponsor, or

(3) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(f) *What will be stated in the published approval for a new animal drug intended for use in liquid feed?* The approval of a new animal drug intended for use in liquid feed as published in this subchapter will include the following requirements:

(1) The formula and/or specifications of the liquid medicated feed, where the owner of this information requests such publication; and/or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(g) *When is a medicated feed mill license required for the manufacture of a liquid medicated feed?* An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All liquid medicated feeds that contain a Category II drug, and

(2) Liquid medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

(h) *What measures are in place to prevent certain drugs, approved for use in animal feed or drinking water but not in liquid medicated feed, from being diverted to use in liquid feeds?* Any product containing any form of bacitracin, oxytetracycline, or chlortetracycline, intended for oral administration via animal feed and/or drinking water, and not approved for use in a liquid medicated feed must include in its labeling the following statement: ''FOR USE IN _____ ONLY. NOT FOR USE IN LIQUID MEDICATED FEEDS.'' The blank