

## Food and Drug Administration, HHS

## § 558.3

558.575 Sulfadimethoxine and ormetoprim.  
558.582 Sulfamerazine.  
558.586 Sulfaquinoxaline.  
558.600 Thiabendazole.  
558.612 Tiamulin.  
558.618 Tilmicosin.  
558.625 Tylosin.  
558.630 Tylosin and sulfamethazine.  
558.633 Tylvalosin.  
558.635 Virginiamycin.  
558.665 Zilpaterol.  
558.680 Zoalene.

AUTHORITY: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

SOURCE: 40 FR 13959, Mar. 27, 1975, unless otherwise noted.

### 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 major species for which they are approved or are approved for use only in minor species.

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

(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 of this

chapter or an index listing granted under § 516.151 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 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 drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act, a conditionally approved application filed pursuant to section 571 of the Federal Food, Drug, and Cosmetic Act, or an index listing under section 572 of the Federal Food, Drug, and Cosmetic Act to use under the professional supervision of a licensed veterinarian. Use of animal feed bearing or containing a VFD drug must be authorized by a lawful veterinary feed directive.

(7) A “veterinary feed directive” is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a VFD drug or combination 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 animal feed bearing or containing a VFD drug or combination VFD drug to treat the client’s animals only in accordance with the conditions for use approved, conditionally approved, or indexed by the Food and Drug Administration.

(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 person. Such other person may be another distributor or the client-recipient of a 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 (nonverbal) communication provided to a distributor (consignor) from another distributor (consignee). An acknowledgment letter must be provided either in hardcopy or through electronic media and must affirm:

(i) That the distributor will not ship such VFD feed to an animal production facility that does not have a VFD,

(ii) That the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter, and

(iii) That the distributor has complied with the distributor notification requirements of § 558.6(c)(5).

(12) A “combination veterinary feed directive (VFD) drug” is a combination new animal drug (as defined in § 514.4(c)(1)(i) of this chapter) intended for use in or on animal feed which is limited by an approved application filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act, a conditionally approved application filed under section 571 of the Federal Food, Drug, and Cosmetic Act, or an index listing under section 572 of the Federal Food, Drug, and Cosmetic Act to use under the professional supervision of a licensed veterinarian, and at least one of the new animal drugs in the combination is a VFD drug. Use of animal feed bearing or containing a combination VFD drug must be authorized by a lawful VFD.

(13) “Major species” means cattle, horses, swine, chickens, turkeys, dogs, and cats.

(14) “Minor species” means animals, other than humans, that are not major species.

[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; 80 FR 31733, June 3, 2015; 81 FR 57800, Aug. 24, 2016]

#### § 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.