(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 may be filled in with the words: ''DRY FEEDS'', ''DRINKING WATER'', or ''DRY FEEDS AND DRINKING WATER''.

(i) *Can the labeling provisions of paragraph (h) of this section be waived, and how can I apply for a waiver?* (1) The labeling provisions of paragraph (h) of this section may be waived if there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

(2) To obtain a waiver, you must submit a letter requesting a waiver to the Office of New Animal Drug Evaluation (HFV–100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(3) The letter must include a copy of the product label; a description of the formulation; and information to establish that the physical, chemical, or other properties of the new animal drug are such that diversion to use in liquid medicated feed is unlikely.

(j) *What else do I need to know about the labeling provisions of paragraph (h) of this section?* The labeling provisions of paragraph (h) of this section may be implemented without prior approval as provided for in § 514.8(c)(3) of this chapter.

[69 FR 30197, May 27, 2004, as amended at 71 FR 74785, Dec. 13, 2006; 72 FR 69131, Dec. 6, 2007]

§ 558.6 Veterinary feed directive drugs.

(a) *General requirements related to veterinary feed directive (VFD) drugs.* (1) Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.

(2) A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.

(3) Use and labeling of a VFD drug or a combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.

(4) All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form

(electronic or hardcopy). The distributor and client copies may be kept as an electronic copy or hardcopy.

(5) All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA upon request.

(6) All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: ''Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.''

(b) *Responsibilities of the veterinarian issuing the VFD.* (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:

(i) Be licensed to practice veterinary medicine; and

(ii) Be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) as defined by the State. If applicable VCPR requirements as defined by such State do not include the key elements of a valid VCPR as defined in § 530.3(i) of this chapter, the veterinarian must issue the VFD in the context of a valid VCPR as defined in § 530.3(i) of this chapter.

(2) The veterinarian must only issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug.

(3) The veterinarian must ensure that the following information is fully and accurately included on the VFD:

(i) The veterinarian's name, address, and telephone number;

(ii) The client's name, business or home address, and telephone number;

(iii) The premises at which the animals specified in the VFD are located;

(iv) The date of VFD issuance;

(v) The expiration date of the VFD. This date must not extend beyond the expiration date specified in the approval, conditional approval, or index listing, if such date is specified. In cases where the expiration date is not specified in the approval, conditional approval, or index listing, the expiration date of the VFD must not exceed 6 months after the date of issuance;

(vi) The name of the VFD drug(s);

(vii) The species and production class of animals to be fed the VFD feed;

(viii) The approximate number of animals to be fed the VFD feed by the expiration date of the VFD. The approximate number of animals is the potential number of animals of the species and production class identified on the VFD that will be fed the VFD feed or combination VFD feed at the specified premises by the expiration date of the VFD;

(ix) The indication for which the VFD is issued;

(x) The level of VFD drug in the VFD feed and duration of use;

(xi) The withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;

(xii) The number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing. In cases where reorders (refills) are not specified on the labeling for an approved, conditionally approved, or index listed VFD drug, reorders (refills) are not permitted;

(xiii) The statement: ''Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.'';

(xiv) An affirmation of intent for combination VFD drugs as described in paragraph (6) of this section; and

(xv) The veterinarian's electronic or written signature.

(4) The veterinarian may, at his or her discretion, enter the following information on the VFD to more specifically identify the animals authorized to be treated/fed the VFD feed:

(i) A more specific description of the location of animals (*e.g.*, by site, pen, barn, stall, tank, or other descriptor that the veterinarian deems appropriate);

(ii) The approximate age range of the animals;

(iii) The approximate weight range of the animals; and

(iv) Any other information the veterinarian deems appropriate to identify the animals specified in the VFD.

(5) For VFDs intended to authorize the use of an approved, conditionally approved, or indexed combination VFD drug that includes more than one VFD drug, the veterinarian must include the drug-specific information required in paragraphs (b)(3)(vi), (ix), (x), and (xi) of this section for each VFD drug in the combination.

(6) The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or may expand such authorization to allow the use of the cited VFD drug(s) along with one or more over-the-counter (OTC) animal drugs in an approved, conditionally approved, or indexed combination VFD drug. The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

(i) ''This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.''

(ii) ''This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.'' [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]

(iii) ''This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.''

(7) The veterinarian must issue a written (nonverbal) VFD.

(8) The veterinarian must send a copy of the VFD to the distributor via hardcopy, facsimile (fax), or electronically. If in hardcopy, the veterinarian must send the copy of the VFD to the distributor either directly or through the client.

(9) The veterinarian must provide a copy of the VFD to the client.

(c) *Responsibilities of any person who distributes an animal feed containing a VFD drug or a combination VFD drug.* (1) The distributor is permitted to fill a VFD only if the VFD contains all the information required in paragraph (b)(3) of this section.

(2) The distributor is permitted to distribute an animal feed containing a VFD drug or combination VFD drug only if it complies with the terms of the VFD and is manufactured and labeled in conformity with the approved, conditionally approved, or indexed conditions of use for such drug.

(3) The distributor must keep records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years.

(4) In addition to other applicable recordkeeping requirements found in this section, if the distributor manufactures the animal feed bearing or containing the VFD drug, the distributor must also keep VFD feed manufacturing records for 1 year in accordance with part 225 of this chapter. Such records must be made available for inspection and copying by FDA upon request.

(5) A distributor of animal feed containing a VFD drug must notify FDA prior to the first time it distributes animal feed containing a VFD drug. The notification is required one time per distributor and must include the following information:

(i) The distributor's complete name and business address;

(ii) The distributor's signature or the signature of the distributor's authorized agent; and

(iii) The date the notification was signed.

(6) A distributor must also notify FDA within 30 days of any change in ownership, business name, or business address.

(7) The notifications cited in paragraphs (c)(5) and (6) of this section must be submitted to the Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV–220), 12225 Wilkins Ave., Rockville, MD 20852, Fax: 240–453–6882, or email (via attachment): *MedicatedFeedsTeamMail@fda.hhs.gov*.

(8) A distributor is permitted to distribute a VFD feed to another distributor only if the originating distributor (consignor) first obtains a written (nonverbal) acknowledgment letter, as defined in § 558.3(b)(11), from

the receiving distributor (consignee) before the feed is shipped. Consignor distributors must retain a copy of each consignee distributor's acknowledgment letter for 2 years.

[80 FR 31733, June 3, 2015; 80 FR 35841, June 23, 2015, as amended at 85 FR 50784, Aug. 18, 2020]

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

§ 558.55 Amprolium.

(a) *Specifications.* Type A medicated article containing 25 percent amprolium.

(b) *Sponsor.* No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(e) *Conditions of use*—(1) *Cattle.* It is used as follows:

Amprolium in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 11, 350; to provide 5 milligrams per kilogram of body weight per day.	Calves: As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii.*	Top-dress on or mix in the daily ration. Feed for 21 days when experience indicates that coccidiosis is likely to be a hazard, as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	016592
(ii) 113.5 to 11, 350; to provide 10 milligrams per kilogram of body weight per day.	Calves: As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zuernii.*	Top-dress on or mix in the daily ration. Feed for 5 days as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	016592

(2) *Chickens.* It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5	.....	Replacement chickens: For development of active immunity to coccidiosis.	Feed continuously until onset of production as follows:	016592

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Amprolium in grams per ton	Amprolium in grams per ton	Amprolium in grams per ton
Severe exposure to coccidiosis	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 36.3 to 113.5	Bacitracin methylenedisalicylate 4 to 50.	Replacement chickens: For development of active immunity to coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed according to subtable in item (i). Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771