

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 per-

cent 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

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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) 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 or index listed indications for use.

(v) Name of the animal drug.

(vi) Level of animal drug in the feed, and the amount of feed required to treat the animals in paragraph (a)(4)(ii) of this section.

(vii) Feeding instructions with the withdrawal time.

(viii) Any special instructions and cautionary statements necessary for use of the drug in conformance with the approval.

(ix) Expiration date of the VFD.

(x) Number of refills (reorders) if necessary and permitted by the approval.

(xi) Your license number and the name of the State issuing the license.

(xii) The statement: “Extra-label use, (i.e., use of this VFD feed in a manner other than as provided for in the VFD drug approval) is strictly prohibited.”

(xiii) Any other information required by the VFD drug approval regulation.

(5) You must produce the VFD in triplicate.

(6) You must issue a VFD only for the approved or indexed conditions and indications for use of the VFD drug.

(b) What must I do with the VFD if I am a veterinarian?

(1) You must give the original VFD to the feed distributor (directly or through the client).

(2) You must keep one copy of the VFD.

(3) You must give the client a copy of the VFD.

(4) You may send a VFD to the client or distributor by facsimile or other electronic means provided you assure that the distributor receives the original signed VFD within 5 working days of receipt of the facsimile or other electronic order.

(5) You may not transmit a VFD by telephone.

(c) What are the VFD recordkeeping requirements?

(1) The VFD feed distributor must keep the VFD original for 2 years from the date of issuance. The veterinarian and the client must keep their copies for the same period of time.