

4. Section 558.5 is revised to read as follows:

§ 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) of this chapter); or
- (2) Type C feed that is intended for:
 - (i) Further manufacture of another Type C feed; or
 - (ii) Top-dressing (adding on top of the usual ration) (§ 558.3(b)(4) of this chapter).

(b) *How is liquid free-choice medicated feed regulated?* Liquid free-choice medicated feed is covered by this section and by § 510.455 of this chapter.

(c) *What types of approvals are required for new animal drugs intended for use in liquid feed?* New animal drugs intended for use in liquid feed must be approved for such use under section 512 of the act, as:

- (1) An original NADA;
- (2) A supplemental NADA; or
- (3) An abbreviated NADA.

(d) *What are the approval requirements for new animal drugs intended for use in liquid feed?* (1) An approval under section 512 of the act is required for any new animal drug intended for use in a liquid feed; and

(2) An approved NADA for a drug intended for use in liquid feed must contain the following information:

(i) Data, or a reference to data in an MF, that shows the relevant ranges of conditions under which the drug will be chemically stable in liquid feed under actual field use conditions; and

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

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

(A) 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.

(B) 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:

(1) Directly in the NADA;

(2) By a sponsor; or

(3) To a master file (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:

(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:

(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 waiver?* (1) The labeling provisions of paragraph (h) 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 Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Office of New Animal Drug Evaluation (HFV-100), 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)?* The labeling provisions of paragraph (h) may be implemented without prior approval as provided for in § 514.8(d) and (e) of this chapter.

§ 558.95 [Amended]

5. Section 558.95 *Bambermycins* is amended in paragraph (d)(4)(iii)(d) by removing the last sentence.

§ 558.305 [Amended]

6. Section 558.305 *Laidlomycin* is amended in paragraphs (c)(1)(i) and (c)(1)(ii) by removing "Type B" whenever it appears.

§ 558.311 [Amended]

7. Section 558.311 *Lasalocid* is amended:

a. In paragraphs (d)(1)(i), (d)(1)(ii), (d)(2), (d)(3), (d)(3)(iii), and (d)(4) by removing "Type B" wherever it appears;

b. In paragraph (d)(2) by removing the last sentence;

c. In paragraphs (d)(2), (d)(3), and (d)(3)(iii) by removing "positionally" and by adding in its place "physically";

d. In paragraph (d)(3)(ii) by removing "positional" and by adding in its place "physical";

e. In paragraph (d)(3)(iii) by removing the second complete sentence

"Approval of the supplement will not be published in the **Federal Register** because such approval will not affect or alter conditions or use of the product in the new animal drug application or the regulation."; and in the third complete sentence by removing "will, however, provide" and by adding in its place "will provide";

f. In paragraph (d)(3)(iii) by removing the phrase "submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for liquid Type B feed" and by adding in its place the phrase "manufacture under a medicated feed mill license the liquid medicated feed described in the master file";

g. In paragraph (e)(2)(iv) by removing the phrase "; each use of this Type C free-choice feed must be the subject of an approved FD-1900 as provided in § 510.455 of this chapter."; and

h. In paragraph (e)(3)(iv) by removing the last sentence.

§ 558.342 [Amended]

8. Section 558.342 *Melengestrol* is amended in paragraphs (d)(1)(i) and (d)(1)(ii) by removing the phrase "Type B or C"; and in paragraph (d)(2) by removing "positionally" and by adding in its place "physically".