4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket No. FDA-2014-N-0002]

New Animal Drugs for Use in Animal Feeds; Withdrawal of Approval of New Animal Drug Applications; Bambermycins; Hygromycin B; Lincomycin; Pyrantel; Tylosin; Tylosin and Sulfamethazine; Virginiamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of 19 new animal drug applications (NADAs) for certain Type A medicated articles and Type B medicated feeds. This action is being taken at the sponsors' request because these products are no longer manufactured or marketed.

DATES: This final rule is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following 5 sponsors have requested that FDA withdraw approval of the 19 NADAs listed in the following tables because the products are no longer manufactured or marketed:

- ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115:

NADA	Product Name
091-582[1]	Gilt Edge TYLAN (tylosin phosphate) Mix
108-484[1]	HFA Tylosin-10 Plus Sulfa (tylosin phosphate and sulfamethazine)
110-045[1]	Good Life TYLAN 10 (tylosin phosphate) Premix
110-439[1]	HFA HYGROMIX 0.48 (hygromycin B) Medicated Premix
128-411[1]	TYLAN 5 Sulfa (tylosin phosphate and sulfamethazine) Premix

- Micro Beef Technologies LTD, P.O. Box 9262, Amarillo, TX 79105:

NADA	Product Name
138-187[1]	TYLAN 40 or 100 (tylosin phosphate)

- Ridley USA, Inc. d/b/a Ridley Feed Ingredients, 1609 First Ave., P.O. Box 110, Mendota, IL 61342:

NADA	Product Name
099-468[1]	Waynextra for Swine (tylosin phosphate)
131-958[1]	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine)
132-136	Ban-A-Worm II (pyrantel tartrate)

- Provimi North America, Inc., 6531 State Rte. 503, Lewisburg, OH 45338:

NADA	Proprietary Name
103-089[1]	TYLAN 5, 10, 20, or 40 (tylosin phosphate)
118-814	WORM-BAN 5 or 10 (pyrantel tartrate)
127-508[1]	HYGROMIX 0.6 (hygromycin B)
131-413	FLAVOMYCIN 0.4 or 2 (bambermycins)
133-333[1]	STAFAC 10 (virginiamycin)

- Virbac AH, Inc., 3200 Meacham Blvd., Fort Worth, TX 76137:

NADA	Proprietary Name
013-214[1]	PURINA HYGROMIX (hygromycin B) for Swine
042-660[1]	PURINA Pork-Plus (tylosin phosphate and sulfamethazine)
043-387[1]	PURINA Hog Plus II (tylosin phosphate)
099-767[1]	PURINA TYLAN 40 (tylosin) Plus Sulfamethazine
132-574[1]	PURINA Check-R-Ton Ll (lincomycin hydrochloride)

[1]The NADAs listed were identified as being affected by guidance for industry (GFI) #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209," December 2013.

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of the NADAs listed in this document, and all supplements and amendments thereto, is withdrawn. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

In addition, FDA has noticed that conditions of use continue to be listed for an NADA that was voluntarily withdrawn in 1989. At this time, the regulations are being amended to remove the sponsor listing from the tables in 21 CFR 510.600(c) and the drug labeler code from 21 CFR 558.625. This action is being taken to improve the accuracy of the regulations.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600, in the table in paragraph (c)(1), remove the entries for "Gossett Nutrition, Inc.", "Micro Beef Technologies LTD", "Provimi North America, Inc.", and "Wayne Feed Division, Continental Grain Co."; and in the table in paragraph (c)(2), remove the entries for "017790", "034936", "047126", and "050972".

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.95 [Amended]

4. In § 558.95, in paragraph (a)(2), remove "Nos. 012286 and 017790" and in its place add "No. 012286"; and in paragraphs (d)(2)(i) and (ii), and paragraphs (d)(3)(i) and (ii), in the "Sponsor" column, remove "017790".

§ 558.274 [Amended]

5. In § 558.274, in paragraph (a) introductory text, remove "or Type B medicated feeds"; remove paragraphs (a)(2) and (a)(3); redesignate paragraph (a)(4) as paragraph (a)(2); and in paragraphs (c)(1)(i) and (c)(2)(i), in the "Sponsor" column, remove "012286" and "017790".

6. In § 558.325, redesignate paragraphs (a) through (d) as paragraphs (b) through (e), add new paragraph (a), revise newly redesignated paragraph (b), and in newly redesignated paragraph (e)(2), in the "Sponsor" column, remove "051311" wherever it occurs.

The addition and revision read as follows:

§ 558.325 Lincomycin.

(a) Specifications. Type A medicated articles containing 20 or 50 grams per pound lincomycin as lincomycin hydrochloride.

(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

* * * * *

§ 558.485 [Amended]

7. In § 558.485, remove and reserve paragraphs (b)(3) and (b)(6).

§ 558.625 [Amended]

8. In § 558.625:

a. Remove paragraphs (b)(2) through (24), (b)(26) through (38), (b)(40) through (53), and (b)(55) through (88); and

b. Redesignate paragraphs (b)(25), (b)(39), (b)(54), (b)(89), and (b)(90) as paragraphs (b)(2) through (6).

9. In § 558.630, revise paragraph (b) to read as follows:

§ 558.630 Tylosin and sulfamethazine.

* * * * *

(b) Approvals. See sponsor in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000986: 10 or 40 grams per pound each for use as in paragraph (e)(2)(i) of this section; 5, 10, 20, or 40 grams per pound each for use as in paragraph (e)(2)(ii) of this section; and 40 grams per pound each for use as in paragraph (e)(2)(iii) of this section.

(2) No. 054771: 5, 10, 20, or 40 grams per pound each for use as in paragraph (e)(2)(ii) of this section.

* * * * *

10. In § 558.635, revise paragraph (a) to read as follows:

§ 558.635 Virginiamycin.

(a) Approvals. See sponsors in §510.600(c) of this chapter:

(1) No. 066104: Type A medicated articles containing 5, 10, 20, 50, or 227 grams per pound virginiamycin for use as in paragraph (d) of this section; and 136.2 grams per pound for use as in paragraph (d)(3) of this section.

(2) No. 054771: Type A medicated articles containing 10 grams per pound virginiamycin for use as in paragraphs (d)(1)(iv) and (v) of this section.

* * * * *

Dated: April 4, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014-08011 Filed 04/09/2014 at 8:45 am; Publication Date: 04/10/2014]