

instituted and their existence has been made public, unless one of the exceptions in section 301(l)(1) to (l)(4) applies. In our review of this petition, FDA did not consider whether section 301(l) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(l) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(l) of the FD&C Act applies.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Section 173.356 is added to subpart D to read as follows:

§ 173.356 Hydrogen peroxide.

Hydrogen peroxide (CAS Reg. No. 7722-84-1) may be safely used to treat

food in accordance with the following conditions:

(a) The additive meets the specifications of the *Food Chemicals Codex*, 7th ed. (2010), pp. 496 and 497, which is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) The additive is used as an antimicrobial agent in the production of modified whey (including, but not limited to, whey protein concentrates and whey protein isolates) by ultrafiltration methods, at a level not to exceed 0.001 percent by weight of the whey, providing that residual hydrogen peroxide is removed by appropriate chemical or physical means during the processing of the modified whey.

Dated: February 16, 2011.

Susan M. Bernard,
Acting Director, Office of Regulations, Policy and Social Services, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

[Docket No. FDA-2011-N-0003]

Animal Drugs, Feeds, and Related Products; Withdrawal of Approval of a New Animal Drug Applications; Phenylbutazone; Pyrantel; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of eight new animal drug applications (NADAs). In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of these NADAs.

DATES: This rule is effective March 14, 2011.

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, e-mail: john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The sponsors have requested that FDA withdraw approval of the three NADAs listed in table 1 of this document because the products are no longer manufactured or marketed:

TABLE 1—VOLUNTARY REQUESTS FOR WITHDRAWAL OF APPROVAL OF THREE NADAS

| Sponsor | NADA No. product (established name of drug) | 21 CFR section affected (sponsor drug labeler code) |
|---|--|---|
| First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123 | NADA 48-647; Phenylbutazone Boluses (phenylbutazone). | § 520.1720a (058829). |
| Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247 ... | NADA 96-161; Hy-Con TYLAN Premix (tylosin phosphate). | § 558.625 (035369). |
| Triple "F", Inc., 10104 Douglas Ave., Des Moines, IA 50322. | NADA 119-062; Cadco-BN-10 BANMINTH Premix (pyrantel tartrate). | § 558.485 (011490). |

Truow Nutrition, Inc., 1590 Todd Farm Dr., Elgin, IL 60123 (Truow) has informed FDA that it is the owner of five feed premix NADAs previously owned by milling companies which it has purchased. NADA 100-352 was owned by NutriBasics Co., last doing

business at P.O. Box 1014, Wilmar, MN 56201. NADA 107-002 and NADA 123-000 were owned by Seeco, Inc., also last doing business at P.O. Box 1014, Wilmar, MN 56201. NADA 133-833 and NADA 135-243 were owned by Southern Micro-Blenders, Inc., last

doing business at 3801 N. Hawthorne St., Chattanooga, TN 37406. Truow has requested that FDA withdraw approval of the five NADAs in table 2 of this document because they are no longer manufactured or marketed:

TABLE 2—VOLUNTARY REQUESTS FOR WITHDRAWAL OF APPROVAL OF FIVE NADAs BY TRUOW NUTRITION, INC.

| Previous sponsor | NADA No. product (established name of drug) | 21 CFR section affected (sponsor drug labeler code) |
|--|---|---|
| NutriBasics Co., P.O. Box 1014, Wilmar, MN 56201 | NADA 100–352; Seeco T–10 Premix (tylosin phosphate). | § 558.625 (053740). |
| Seeco, Inc., P.O. Box 1014, Wilmar, MN 56201 | NADA 107–002; Seeco TYLAN-Sulfa 10 Premix (tylosin phosphate and sulfamethazine). | Not codified. |
| Seeco, Inc., P.O. Box 1014, Wilmar, MN 56201 | NADA 123–000; Super Swine Wormer B–9 BANMINTH(pyrantel tartrate). | § 558.485 (011749). |
| Southern Micro-Blenders, Inc., 3801 N. Hawthorne St., Chattanooga, TN 37406. | NADA 133–833; TYLAN 10 Premix (tylosin phosphate) | § 558.625 (049685). |
| Southern Micro-Blenders, Inc., 3801 N. Hawthorne St., Chattanooga, TN 37406. | NADA 135–243; Swine Guard-BN BANMINTH Premix (pyrantel tartrate). | § 558.485 (049685). |

In a notice published elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADA 48–647, 96–161, 100–352, 107–002, 119–062, 123–000, 133–833, and 135–243, and all supplements and amendments thereto, is withdrawn, effective March 14, 2011. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these withdrawals of approval.

Following these changes of sponsorship, Yoder Feed, Division of Yoder, Inc., Triple “F”, Inc., NutriBasics Co., Seeco, Inc., and Southern Micro-Blenders, Inc., are no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

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 Part 520

Animal drugs.

21 CFR Part 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, 520, 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.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entries for “Triple “F”, Inc.” and “Yoder Feed, Division of Yoder, Inc.”; and in the table in paragraph (c)(2), remove the entries for “011490”, “011749”, “035369”, “049685”, and “053740”.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 4. In § 520.1720a, revise paragraph (b)(6) to read as follows:

§ 520.1720a Phenylbutazone tablets and boluses.

* * * * *

(b) * * *

(6) No. 058829 for use of 100-mg or 1-g tablets in dogs and horses.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 6. In § 558.485, revise the section heading and paragraph (b)(3) to read as follows:

§ 558.485 Pyrantel.

* * * * *

(b) * * *

(3) Nos. 010439, 012286, 016968, and 017790: 9.6 and 19.2 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

* * * * *

§ 558.625 [Amended]

■ 7. In § 558.625, remove and reserve paragraphs (b)(8), (b)(38), and (b)(80).

Dated: February 18, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–4546 Filed 3–1–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA–2010–N–0534]

RIN 0910–AG58

New Animal Drugs for Minor Use and Minor Species; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of March 30, 2011, for the final rule that appeared in the **Federal Register** of November 15, 2010 (75 FR 69586). The direct final rule amends the regulations regarding new animal drugs for minor use and minor species (MUMS) to update language and clarify the intent of the regulations consistent with the preambles to the proposed and final rules. This document confirms the effective date of the direct final rule. **DATES:** Effective date confirmed: March 30, 2011.

FOR FURTHER INFORMATION CONTACT: Meg Oeller, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9005, *e-mail:* margaret.oeller@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 15, 2010 (75 FR 69586), FDA solicited comments concerning the direct final rule for a 75-day period ending January 31, 2011. FDA stated that the effective date of the