DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558
[Docket No. FDA–2010–N–0002]

Animal Drugs, Feeds, and Related Products; Withdrawal of Approval of a New Animal Drug Application; Buquinolate; Coumaphos

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 two new animal drug applications (NADAs). In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of three of these NADAs.

DATES: This rule is effective May 17, 2010.

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

SUPPLEMENTARY INFORMATION:

Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166–6812 has requested that FDA withdraw approval of NADA 42–177 for Purina 6 Day Worm–Kill Concentrate (coumaphos) because the product is no longer manufactured or marketed.

In addition, Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017 has requested that FDA withdraw approval of NADA 45–738 for use of LINCOMIX (lincomycin) and BONAID (buquinolate) single-ingredient Type A medicated articles to make two-way, combination drug Type C medicated broiler feed because buquinolate is no longer manufactured or marketed.

In a notice published elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADA 42–117 and NADA 45–738, and all supplements and amendments thereto, is withdrawn, effective May 17, 2010. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these withdrawals of approval.

In 1995, the approval of NADA 34 716 for BONAID Type A medicated article was voluntarily withdrawn (60 FR 37651, July 21, 1995) and approved conditions of use for buquinolate and all its approved combinations in 21 CFR 558.105, including combination with lincomycin under NADA 45–738, were removed (60 FR 39447, July 21, 1995). At this time, the tolerances for residues of buquinolate in edible products of chickens and its listing as a Category I drug in 21 CFR 558.4 are being removed.

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

Animal drugs, Foods.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:


§556.90 [Removed]

2. Remove §556.90.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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


§558.4 [Amended]

4. In §558.4, in paragraph (d), in the “Category I” table, remove the entry for “Buquinolate”.

§558.185 [Amended]

5. In §558.185, remove paragraph (b)(2) and redesignate paragraph (b)(3) as paragraph (b)(2).


Bernadette Dunham,
Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 551

Somalia Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final Rule.

SUMMARY: The Department of the Treasury’s Office of Foreign Assets Control (“OFAC”) is issuing regulations with respect to Somalia to implement Executive Order 13536 of April 12, 2010. OFAC intends to supplement this part 551 with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance and additional general licenses and statements of licensing policy.

DATES: Effective Date: May 5, 2010.

FOR FURTHER INFORMATION CONTACT: Assistant Director for Compliance, Outreach & Implementation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Assistant Director for Policy, tel.: 202/622–4855, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC’s Web site (http://www.treas.gov/ofac). Certain general information pertaining to OFAC’s sanctions programs also is available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Background

On April 12, 2010, the President, invoking the authority of, inter alia, the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), the National Emergencies Act (50 U.S.C. 1601 et seq.), and section 5 of the United Nations Participation Act (22 U.S.C. 287c), issued Executive Order 13536 (75 FR 19869, April 15, 2010) (“E.O. 13536”), effective at 12:01 a.m. eastern daylight time on April 13, 2010. The Department of the Treasury’s Office of Foreign Assets Control is issuing the Somalia Sanctions Regulations, 31 CFR part 551 (the “Regulations”), to implement E.O. 13536, pursuant to authorities delegated to the Secretary of the Treasury in E.O.