

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

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

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: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing 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: Withdrawal of approval is effective April 21, 2014.

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 1st 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 LI (lincomycin hydrochloride).

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of the NADAs listed in this document, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: April 4, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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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.

PEACE CORPS

22 CFR Part 303

RIN 0420-AA29

Freedom of Information Act Administration

AGENCY: Peace Corps.

ACTION: Final rule.

SUMMARY: The final rule updates Peace Corps regulations on the Freedom of Information Act (FOIA) to implement guidance given by the President and the Attorney General regarding discretionary disclosures of records or information exempt from disclosure under the FOIA, whenever disclosure would not foreseeably harm an interest protected by a FOIA exemption. The final rule is based on language used by Department of Justice in its FOIA regulations. The Peace Corps received comments from the National Archives and Records Administration's Office of Government Information Services (OGIS).

DATES: This final rule is effective May 12, 2014.

FOR FURTHER INFORMATION CONTACT: Anne Hughes, Office of the General Counsel, Policy and Program Analyst, 1111 20th Street NW., Washington, DC 20526, and 202-692-2164.

SUPPLEMENTARY INFORMATION: The revisions to the Peace Corps' Freedom of Information Act ("FOIA") regulations would incorporate the disclosure principles contained in President Obama's January 21, 2009 Memorandum regarding FOIA, the Attorney General's FOIA Guidelines to Favor Disclosure and Transparency dated March 19, 2009, and the Guide to the Freedom of Information Act promulgated by the Department of Justice's Office of Information Policy. The final rule deletes unnecessary and superfluous language and ensures the rule is consistent with current law. The final rule inserts additional contact information for the filing of initial FOIA requests; inserts additional contact information for the filing of administrative appeals; and adds two FOIA exemptions: 5 U.S.C. 552(b)8, Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; and (b)9, Geological and geophysical information and data, including maps, concerning wells. The Peace Corps FOIA regulations were last revised May 14, 2007 (72 FR 27055).