



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2016-N-0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 18 new animal drug applications (NADAs) and 2 abbreviated new animal drug applications (ANADAs). These withdrawals of approval of NADAs and ANADAs for antimicrobial drugs of importance to human medicine that are administered to food-producing animals in medicated feed are being made because the products are no longer manufactured or marketed. These actions are consistent with the FDA Center for Veterinary Medicine's initiative for the Judicious Use of Antimicrobials.

DATES: Withdrawal of approval is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is withdrawing approval of 18 NADAs and 2 ANADAs. These applications 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

(<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>). Their withdrawal of approval is consistent with the FDA Center for Veterinary Medicine's initiative for the Judicious Use of Antimicrobials.

Approval of the following applications for new animal drugs administered in medicated feed is being voluntarily withdrawn at the sponsors' requests because these products are no longer manufactured or marketed:

File No.	Product Name	Sponsor
044-820	LINCOMIX (lincomycin)/AMPROL PLUS (amprolium and ethopabate)	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007 (Zoetis Inc.)
044-972	LINCOMIX (lincomycin)/COYDEN (clopidol)	Zoetis Inc.
047-261	LINCOMIX (lincomycin)/DECCOX (decoquinatate)	Zoetis Inc.
047-262	LINCOMIX (lincomycin)/DECCOX (decoquinatate)	Zoetis Inc.
048-954	LINCOMIX (lincomycin)/ZOAMIX (zoalene)	Zoetis Inc.
091-513	STAFAC (virginiamycin) Type A Medicated Article	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666 (Phibro Animal Health Corp.)
092-482	LINCOMIX (lincomycin)/COBAN (monensin)	Zoetis Inc.
093-106	LINCOMIX (lincomycin)/ROBENZ (robenidine)	Zoetis Inc.
101-689	LINCOMIX (lincomycin)/AVATEC (lasalocid)	Zoetis Inc.
122-481	STAFAC (virginiamycin)/COBAN (monensin)	Phibro Animal Health Corp.
122-608	STAFAC (virginiamycin)/AVATEC (lasalocid)	Phibro Animal Health Corp.
122-822	STAFAC (virginiamycin)/AMPROL PLUS (amprolium and ethopabate)	Phibro Animal Health Corp.
137-537	LINCOMIX (lincomycin)/BIO-COX (salinomycin)	Zoetis Inc.
138-792	TYLAN (tylosin)/RUMENSIN (monensin)/MGA (melengestrol acetate)	Zoetis Inc.
138-828	STAFAC (virginiamycin)/BIO-COX (salinomycin)	Phibro Animal Health Corp.
138-904	TYLAN (tylosin)/BOVATEC (lasalocid)/MGA (melengestrol acetate)	Zoetis Inc.
141-110	STAFAC (virginiamycin)/COBAN (monensin)	Phibro Animal Health Corp.
141-150	STAFAC (virginiamycin)/AVATEC (lasalocid)	Phibro Animal Health Corp.
200-092	STAFAC (virginiamycin)/SACOX (salinomycin)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria (Huvepharma EOOD)
200-093	LINCOMIX (lincomycin)/SACOX (salinomycin)	Huvepharma EOOD

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 NADAs 044-820, 044-972, 047-261, 047-262, 048-954, 091-513, 092-482, 093-106, 101-689, 122-481, 122-608, 122-822, 137-537, 138-792, 138-828, 138-904, 141-110, 141-150, 200-092, and 200-093, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: February 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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