



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 11 new animal drug applications (NADAs) and 4 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 being 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 December 30, 2016.

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](mailto:sujaya.dessai@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: FDA is withdrawing approval of 11 NADAs and 4 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Approval of the following applications for new animal drugs administered in medicated feed is being voluntarily withdrawn at the sponsors' requests because these products are no longer manufactured or marketed: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
034-085	LINCOMIX (lincomycin hydrochloride monohydrate) Type A Medicated Article	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007
035-287	OM-5 Premix (oleandomycin) Type A Medicated Article	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666
046-668	Penicillin G Procaine 50% Type A Medicated Article	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666
091-668	CHLORMAX-SP 500 (chlortetracycline, sulfamethazine, penicillin G procaine) Type A Medicated Article	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007
108-116	LINCOMIX (lincomycin) / NICARB (nicarbazine)	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666
133-334	Virginiamycin Type A Medicated Article	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007
139-473	STAFAC (virginiamycin) / STENEROL (halofuginone hydrobromide)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria
140-340	LINCOMIX (lincomycin) / STENOROL (halofuginone hydrobromide)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria

140-443	HYGROMIX 1.6 (hygromycin B) Type A Medicated Article	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007
140-947	LINCOMIX (lincomycin) / MAXIBAN (narsin and nicarbazin)	Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140
141-090	STAFAC (virginiamycin) / CLINICOX (diclazuril)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria
200-171	LINCOMIX (lincomycin) / NICARMIX (nicarbazin)	Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053-120, Campinas, Sao Paulo, Brazil
200-569	TYLAN (tylosin) / SACOX (salinomycin)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria
200-570	TYLOVET 100 (tylosin) / BIO-COX (salinomycin)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria
200-580	TYLOVET 100 (tylosin) / SACOX (salinomycin)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria

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 034-085, 035-287, 046-668, 091-668, 108-116, 133-334, 139-473, 140-340, 140-443, 140-947, 141-090, 200-171, 200-569, 200-570, and 200-580, and all supplements and amendments thereto, is hereby withdrawn, effective December 31, 2016.

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: December 20, 2016.

Tracey H. Forfa,

Deputy Director,

Center for Veterinary Medicine.

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