

■ 42. In § 558.665, remove and reserve paragraphs (e)(5) and (6); remove paragraphs (e)(11) and (12); and add paragraph (f) to read as follows:

§ 558.665 Zilpaterol.

* * * * *

(f) Zilpaterol may also be used in combination with tylosin as in § 558.625.

■ 43. In § 558.680, remove paragraph (d)(1)(x); and add paragraph (e)(3) to read as follows:

§ 558.680 Zoalene.

* * * * *

(e) * * *

(3) Zoalene may also be used in combination with lincomycin as in § 558.325.

Dated: December 20, 2016.

Tracey H. Forfa,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 2016-31083 Filed 12-23-16; 8:45 am]

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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.

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 (nicarbazin) | 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 (narasin 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.

[FR Doc. 2016–31082 Filed 12–23–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2015–F–4282]

Food Additives Permitted in Feed and Drinking Water of Animals; Feed Grade Sodium Formate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of feed grade sodium formate as a feed acidifying agent in complete poultry feeds. This action is in response to a food additive petition filed by BASF Corp.

DATES: This rule is effective December 27, 2016. Submit either written or electronic objections and requests for a hearing by January 26, 2017. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows:

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2015–F–4282 for “Food Additives Permitted in Feed and Drinking Water of Animals; Feed Grade Sodium Formate.” Received objections will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be

made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper objections received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6729, chelsea.trull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of November 24, 2015 (80 FR 73153), FDA announced that we had filed a food additive petition (animal use) (FAP 2293) submitted by BASF Corp., 100 Park Ave., Florham Park, NJ 07932. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of feed grade sodium formate as a feed acidifying agent in complete poultry feeds.

II. Conclusion

FDA concludes that the data establish the safety and utility of feed grade sodium formate for use as a feed acidifying agent in complete poultry feeds and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.