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.


Authorized by Tracey H. Forfa, Deputy Director, Center for Veterinary Medicine.

NOTICE OF WITHDRAWAL OF APPROVAL

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Approval of the following applications for new animal drugs administered in medicated feed is being voluntarily withdrawn at the sponsors’ requests because these products are no longer manufactured or marketed:

<table>
<thead>
<tr>
<th>File No.</th>
<th>Product name</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>034–085</td>
<td>LINCÓMIX (lincomycin hydrochloride monohydrate) Type A Medicated Article</td>
<td>Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.</td>
</tr>
<tr>
<td>091–668</td>
<td>CHLORMAX–SP 500 (chloretetracycline, sulfamethazine, penicillin G procaine) Type A Medicated Article</td>
<td>Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.</td>
</tr>
<tr>
<td>133–334</td>
<td>Virginiamycin Type A Medicated Article</td>
<td>Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.</td>
</tr>
<tr>
<td>139–473</td>
<td>STAFAC (virginiamycin)/STENEROL (halofuginone hydrobromide)</td>
<td>Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.</td>
</tr>
<tr>
<td>140–340</td>
<td>LINCÓMIX (lincomycin)/STENEROL (halofuginone hydrobromide)</td>
<td>Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.</td>
</tr>
<tr>
<td>140–443</td>
<td>HYGROMIX 1.6 (hygromycin B) Type A Medicated Article</td>
<td>Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.</td>
</tr>
<tr>
<td>140–947</td>
<td>LINCÓMIX (lincomycin)/MAXIBAN (narasin and nicarbazin)</td>
<td>Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.</td>
</tr>
<tr>
<td>200–171</td>
<td>LINCÓMIX (lincomycin)/NICARMIX (nicarbazin)</td>
<td>Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.</td>
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<tr>
<td>200–569</td>
<td>TYLAN (tylosin)/SACOX (salinomycin)</td>
<td>Planalquimica Industrial Ltda., Rua das Magnolias nº 2405, Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Paulo, Brazil.</td>
</tr>
<tr>
<td>200–570</td>
<td>TYLOVET 100 (tylosin)/BIO–COX (salinomycin)</td>
<td>Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.</td>
</tr>
<tr>
<td>200–580</td>
<td>TYLOVET 100 (tylosin)/SACOX (salinomycin)</td>
<td>Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.</td>
</tr>
</tbody>
</table>
Food and Drug Administration

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.

ADDRESS: You may submit objections and requests for a hearing by January 26, 2017. See section V of this document for information on the filing of objections.

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 56499, 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 it 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.

95026 Federal Register / Vol. 81, No. 248 / Tuesday, December 27, 2016 / Rules and Regulations