4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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

New Animal Drugs for Use in Animal Feeds; Chlortetracycline and Sulfamethazine; Chlortetracycline; Procaine Penicillin; and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of those parts of a new animal drug application (NADA) for a three-way, fixed-ratio, combination drug Type A medicated article that pertain to use of the procaine penicillin component for growth promotion indications in swine and to reflect the reformulation of the Type A medicated article as a two-way, fixed-ratio, combination drug product without penicillin.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, email: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc. (Zoetis), 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of those parts of NADA 035-688 for AUREOMIX Granular 500 (chlortetracycline, procaine penicillin, and sulfamethazine) Type A

medicated article that pertain to use of the procaine penicillin component for growth promotion indications in swine. Zoetis requested voluntary withdrawal of approval of these indications for use because AUREOMIX Granular 500 Type A medicated article is no longer manufactured.

With the withdrawal of approval of the production indications for procaine penicillin, the product approved under NADA 035-688 was reformulated as AUREOMIX S Granular (chlortetracycline and sulfamethazine) Type A Medicated Article, a two-way, fixed-ratio, combination drug Type A medicated article that does not contain penicillin procaine and is not labeled for production indications.

The Agency has determined under 21 CFR 25.33(a)(3) and (g) that these actions are categorically excluded from the requirement to submit an environmental assessment or an environmental impact statement because they are of a type that do not individually or cumulatively have a significant effect on the human environment.

Elsewhere in this issue of the Federal Register, FDA gave notice that the approval of those parts of NADA 035-688 pertaining to the procaine penicillin component indications for growth promotion and increased feed efficiency in swine is withdrawn, effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided for in the regulatory text of this document, the animal drug regulations are amended to reflect this partial withdrawal of approval and subsequent product reformulation.

NADA 035-688 was 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.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Revise § 558.140 to read as follows:

§ 558.140 Chlortetracycline and sulfamethazine.

(a) Specifications. Type A medicated articles containing:

(1) 35 grams (g) per pound (/lb) each, chlortetracycline and sulfamethazine.

(2) 40 g/lb each, chlortetracycline and sulfamethazine.

(b) Sponsors. See sponsors numbers in § 510.600(c) of this chapter as follow:

(1) Nos. 054771 and 048164 for use of product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(c) Related tolerances. See §§ 556.150 and 556.670 of this chapter.

(d) Conditions of use--(1) Cattle. It is used in feed for beef cattle as follows:

(i) Amount. 350 milligrams per head per day each, chlortetracycline and sulfamethazine.

(ii) Indications for use. Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

(iii) Limitations. Feed for 28 days; withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(2) Swine. It is used in swine feed as follows:

(i) Amount. 100 g/ton each, chlortetracycline and sulfamethazine.

(ii) Indications for use. For reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by Salmonella choleraesuis and vibrionic dysentery); prevention of these diseases during times of stress; and maintenance of weight gains in the presence of atrophic rhinitis.

(iii) Limitations. Feed as the sole ration. Withdraw 15 days prior to slaughter.

§ 558.145 [Amended]

3. In § 558.145, in paragraph (a)(2), remove "Nos. 048164 and 054771" and in its place add "No. 048164".

Dated: June 25, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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