§ 522.814 Eprinomectin.

* * * * *

(d) * * *

(2) *Indications for use.* For the treatment and control of the following internal and external parasites: Gastrointestinal roundworms (adults and fourth-stage larvae) *Bunostomum phlebotomum, Cooperia oncophora, C. punctata, C. surnabada, Trichostrongylus axei, Ostertagia ostertagi* (including inhibited stage); (adults) *Haemonchus placei, Oesophagostomum radiatum, O. lyrata, T. colubriformis;* lungworms (adults) *Dictyocaulus viviparus;* cattle grubs *Hypoderma bovis;* mites *Sarcoptes scabiei* var. *bovis.* Prevents reinfection with *C. oncophora, C. punctata,* and *T. axei* for 100 days following treatment; *H. placei, O. radiatum, O. lyrata,* and *O. ostertagi* for 120 days following treatment; and *B. phlebotomum* and *D. viviparus* for 150 days following treatment.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Animals intended for human consumption must not be slaughtered within 48 days of the last treatment. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 13. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 14. Add 529.382 to read as follows:

§ 529.382 Chloramine-T.

(a) *Specifications.* Chloramine-T trihydrate powder for solution.

(b) *Sponsor.* See No. 086009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.118 of this chapter.

(d) *Conditions of use*—(1) *Freshwater-reared salmonids*—(i) *Amount.* 12 to 20 milligrams per liter (mg/L) water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use.* For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp.

(2) *Walleye*—(i) *Amount.* 10 to 20 mg/L water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use.* For the control of mortality in walleye due to external columnaris disease associated with *Flavobacterium columnare.*

(3) *Freshwater-reared warmwater finfish*—(i) *Amount.* 20 mg/L water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use.* For the control of mortality in freshwater-reared warmwater finfish due to external columnaris disease associated with *F. columnare.*

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 15. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 16. Add § 556.118 to read as follows:

§ 556.118 Chloramine-T.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of chloramine-T is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Fish*—(i) *Muscle/skin (target tissue).* The tolerance for *para*-toluenesulfonamide (marker residue) is 0.90 parts per million.

(ii) [Reserved]

(2) [Reserved]

(c) *Related conditions of use.* See § 529.382 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.4 [Amended]

■ 18. In § 558.4, in paragraph (d), in the ''Category I'' table, remove the entry for ''Niclosamide''.

§ 558.500 [Amended]

■ 19. Amend § 558.500 as follows:

■ a. In the table in paragraphs (e)(1)(ii), (iii), and (iv), in the ''Limitations'' column, add at the end of the entry ''Ractopamine as provided by No. 000986 with tylosin as provided by Nos. 000986 or 016592 in § 510.600(c) of this chapter; or ractopamine as provided by No. 054771 with tylosin as provided by No. 000986 in § 510.600(c) of this chapter.'' and in the ''Sponsor'' column, remove ''000986'' and in its place add ''000986, 016592, 054771'';

■ b. In the table in paragraph (e)(2)(viii), in the ''Limitations'' column, remove ''No. 054771'' and in its place add ''Nos. 000986 and 054771'';

■ c. In the table in paragraph (e)(2)(x), in the ''Limitations'' column, remove ''Nos. 054771 and 021641'' and in its place add ''Nos. 000986 and 054771''; and

■ d. In the table in paragraphs (e)(2)(ix) and (xiii), in the ''Limitations'' column, add at the end of the entry ''Ractopamine as provided by Nos. 000986 or 054771 with tylosin as provided by No. 000986 in § 510.600(c) of this chapter.'' and in the ''Sponsor'' column, remove ''000986'' and in its place add ''000986, 054771''.

Dated: June 25, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–15276 Filed 6–30–14; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2014–N–0002]

Withdrawal of Approval of Part of a New Animal Drug Application; Procaine Penicillin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing 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. This action is being taken at the sponsor's request because the three-way Type A medicated article is no longer manufactured.

DATES: Withdrawal of approval is effective July 2, 2014.

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, *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.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Veterinary Medicine, and in accordance with 21 CFR 514.116 *Notice of withdrawal of approval of application,* notice is given that approval of those parts of NADA 035–688 that pertain to use of procaine penicillin for the production indications of growth promotion and increased feed efficiency in swine are hereby withdrawn, effective July 2, 2014.

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.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these parts of NADA 035–688.

Dated: June 25, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–15273 Filed 6–30–14; 11:15 am]

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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 July 2, 2014.

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 July 2, 2014. 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.