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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 529, 556, and 558

[Docket No. FDA–2014–N–0002]

New Animal Drugs; Afoxalaner; Ceftiofur Crystalline Free Acid; Chloramine-T; Clodronate; Enrofloxacin; Eprinomectin; Fluralaner; Ivermectin and Praziquantel; Niclosamide; Ractopamine; Tylosin; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during April and May 2014. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to remove an obsolete entry for a drug for which approval was withdrawn in 1996.

DATES: This rule is effective July 2, 2014.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during April and May 2014, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at *http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

Also, the regulations are being amended in 21 CFR 510.600 to reflect a change of address for Dechra, Ltd.; in 21 CFR 522.313a to reflect the previous approval of revised food safety warnings for ceftiofur sodium powder for injection; and in 21 CFR 558.4 to remove a listing for niclosamide which remained codified, in error, following the voluntary withdrawal of approval of the sole NADA for a niclosamide medicated feed (61 FR 34727, July 3, 1996). These amendments are being made to improve the accuracy of the regulations.

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.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING APRIL AND MAY 2014

NADA/A ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
141–421	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	DUOCARE (ivermectin 1.87% and praziquantel 23.38%) Paste.	Original approval for the treatment and control of gastrointestinal nematodes, cestodes, and tapeworms parasites in horses over 5 months of age.	520.1198	yes	CE.[1] [2]
141–423	Axcentive SARL, Chemin de Champouse, Quartier Violesi, 13320 Bouc Bel Air, France.	HALAMID (chloramine-T powder for immersion) Aqua.	Original approval for control of mortality in certain freshwater fish due to *Flavobacterium* spp.	510.600 529.382 556.118	yes	EA/FONSI.[3]

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING APRIL AND MAY 2014—Continued

NADA/A ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
141–426	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901.	BRAVECTO (fluralaner) Chewable Tablets for Dogs.	Original approval for the treatment and prevention of flea infestations, and the treatment and control of tick infestations in dogs and puppies.	520.998	yes	CE.[1 2]
141–427	Dechra, Ltd., Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom.	OSPHOS (clodronate injection).	Original approval for the control of clinical signs associated with navicular syndrome in horses.	522.454	yes	CE.[1 2]
013–076[4]	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	TYLAN (tylosin tartrate) Soluble Powder.	Supplemental approval of a change in marketing status from over-the-counter (OTC) to by veterinary prescription (Rx).	520.2640	no	CE.[1 5]
141–327	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide.	Supplemental approval adding treatment and control of a gastrointestinal roundworm with 150 days of persistent effectiveness.	522.814	yes	CE.[1 5]
141–406	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	NEXGARD (afoxolaner) Chewable Tablets.	Supplemental approval for the treatment and control of two additional species of tick in dogs and puppies.	520.43	yes	CE.[1 2]
200–513	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	ENROFLOX (enrofloxacin) Injection for Dogs 2.27%.	Original approval as a generic copy of NADA 140–913.	522.812	yes	CE.[1 5]
200–530	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	TYLOVET 100 (tylosin phosphate) plus PAYLEAN (ractopamine HCl) Type B and C medicated feeds.	Original approval as a generic copy of NADA 141–172.	558.500	yes	CE.[1 6]
200–558	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	ENGAIN 9 and 45 (ractopamine HCl) plus TYLAN 100 (tylosin phosphate) Type B and C medicated feeds.	Original approval as a generic copy of NADA 141–172.	New 522.500	yes	CE.[1 6]
200–561	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	ACTOGAIN 45 (ractopamine HCl), RUMENSIN (monensin), and TYLAN 100 (tylosin phosphate) Type B and C medicated feeds.	Original approval as a generic copy of NADA 141–224.	558.500	yes	CE.[1 6]

[1] The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

[2] CE granted under 21 CFR 25.33(d)(1).

[3] The Agency has carefully considered an EA of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).

[4] The NADA listed 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.

[5] CE granted under 21 CFR 25.33(a)(1).

[6] CE granted under 21 CFR 25.33(a)(2).

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 529, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for ''Axcentive SARL'' and revise the entry for ''Dechra, Ltd.''; and in the table in paragraph (c)(2), revise the entry for ''043264'' and numerically add an entry for ''086009'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Axcentive SARL, Chemin de Champouse, Quartier Violesi, 13320 Bouc Bel Air, France	086009
* * * * *	
Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom	043264
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
043264	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom
* * * * *	
086009	Axcentive SARL, Chemin de Champouse, Quartier Violesi, 13320 Bouc Bel Air, France
* * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 4. In § 520.43, revise paragraph (c)(2) to read as follows:

§ 520.43 Afoxolaner.

* * * * *

(c) * * *

(2) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*); and for the treatment and control of black-legged tick (*Ixodes scapularis*), American Dog tick (*Dermacentor variabilis*), and lone star tick (*Amblyomma americanum*) infestations in dogs and puppies 8 weeks of age and older, weighing 4 lb of body weight or greater, for 1 month.

* * * * *

■ 5. Section 520.998 is added to read as follows:

§ 520.998 Fluralaner.

(a) *Specifications.* Each chewable tablet contains 112.5, 250, 500, 1000, or 1400 milligrams (mg) fluralaner.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally as a single dose every 12 weeks according to the label dosage schedule to provide a minimum dose of 11.4 mg per pound (/lb) (25 mg per kilogram) body weight. May be administered every 8 weeks in case of potential exposure to *Amblyomma americanum* ticks.

(2) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick)] for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater; for the treatment and control of *A. americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 6. In § 520.1198, add paragraphs (a)(3), (b)(3), and (d)(1)(iii); and revise paragraph (d)(2) to read as follows:

§ 520.1198 Ivermectin and praziquantel paste.

(a) * * *

(3) 0.0187 mg (1.87 percent) ivermectin and 0.2338 mg (23.38 percent) praziquantel.

(b) * * *

(3) No. 050604 for use of products described in paragraph (a)(3) of this section as in paragraphs (d)(1)(iii), (d)(2)(iii) and (d)(3) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) 200 mcg/kg ivermectin (91 mcg/lb) and 2.5 mg/kg praziquantel (1.14 mg/lb).

(2) *Indications for use*—(i) For treatment and control of the following parasites: Tapeworms—*Anoplocephala perfoliata;* Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus, Triodontophorus* spp. including *T. brevicauda* and *T. serratus,* and *Craterostomum acuticaudatum;* Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocyclus* spp. including *C. coronatus, C. labiatus,* and *C. labratus; Cyathostomum* spp. including *C. catinatum* and *C. pateratum; Cylicocyclus* spp. including *C. insigne, C. leptostomum, C. nassatus,* and *C. brevicapsulatus; Cylicodontophorus* spp.; *Cylicostephanus* spp. including *C. calicatus, C. goldi, C. longibursatus,* and *C. minutus,* and *Petrovinema poculatum;* Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi;* Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum;* Hairworms (adults)—*Trichostrongylus axei;* Large-mouth Stomach Worms (adults)—*Habronema muscae;* Bots (oral and gastric stages)—*Gasterophilus* spp.

including *G. intestinalis* and *G. nasalis;* Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi;* Intestinal Threadworms (adults)—*Strongyloides westeri;* Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae of *Onchocerca* sp.

(ii) For treatment and control of the following parasites: Tapeworms—*Anoplocephala perfoliata;* Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus, Triodontophorus* spp.; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Cyathostomum* spp.; *Cylicocyclus* spp.; *Cylicostephanus* spp., *Cylicodontophorus* spp.; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi;* Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum;* Hairworms (adults)—*Trichostrongylus axei;* Large-mouth Stomach Worms (adults)—*Habronema muscae;* Bots (oral and gastric stages)—*Gasterophilus* spp.; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi;* Intestinal Threadworms (adults)—*Strongyloides westeri;* Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(iii) For treatment and control of the following parasites in horses over 5 months of age: Tapeworms—*Anoplocephala perfoliata;* Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus, Triodontophorus* spp. including *T. brevicauda* and *T. serratus,* and *Craterostomum acuticaudatum;* Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocyclus* spp. including *C. coronatus, C. labiatus,* and *C. labratus; Cyathostomum* spp. including *C. catinatum* and *C. pateratum; Cylicocyclus* spp. including *C. insigne, C. leptostomum, C. nassatus,* and *C. brevicapsulatus; Cylicodontophorus* spp.; *Cylicostephanus* spp. including *C. calicatus, C. goldi, C. longibursatus,* and *C. minutus,* and *Petrovinema poculatum;* Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi;* Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum;* Hairworms (adults)—*Trichostrongylus axei;* Large-mouth Stomach Worms (adults)—*Habronema muscae;* Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis;* Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi;* Intestinal Threadworms (adults)—*Strongyloides westeri;* Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae of *Onchocerca* sp.

* * * * *

■ 7. Amend § 520.2640 as follows:
■ a. Revise paragraph (b);
■ b. Redesignate paragraph (d) as (e);
■ c. Add new paragraph (d); and
■ d. Revise newly designated paragraph (e)(2)(ii).

The addition and revisions read as follows:

§ 520.2640 Tylosin.

* * * * *

(b) *Sponsors*—(1) No. 000986 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii)(A), (e)(2)(iii), (e)(3), and (e)(4) of this section.

(2) Nos. 016592 and 061623 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii)(B), (e)(2)(iii), (e)(3), and (e)(4) of this section.

* * * * *

(d) *Special considerations.* For No. 000986, labeling shall bear ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(e) * * *

(2) * * *

(ii) *Indications for use*—(A) For the reduction in severity of effects of infectious sinusitis associated with *Mycoplasma gallisepticum.*

(B) For maintaining weight gain and feed efficiency in the presence of infectious sinusitis associated with *Mycoplasma gallisepticum* sensitive to tylosin.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 9. In 522.313a, remove paragraph (d); redesignate paragraph (e) as paragraph (d); and revise newly redesignated paragraphs (d)(1)(iii), (d)(2)(iii), and (d)(3)(iii) to read as follows:

§ 522.313a Ceftiofur crystalline free acid.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Following label use as a single treatment, a 14-day pre-slaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in swine for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved, major food-producing species/production classes.

(2) * * *

(iii) *Limitations.* Following label use as either a single-dose or 2-dose regimen, a 13-day pre-slaughter withdrawal period is required after the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved, major food-producing species/production classes.

(3) * * *

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 10. Add § 522.454 to read as follows:

§ 522.454 Clodronate.

(a) *Specifications.* Each milliliter of solution contains 60 milligrams (mg) clodronate disodium.

(b) *Sponsor.* See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1.8 mg per kilogram of body weight by intramuscular injection up to a maximum dose of 900 mg per horse.

(2) *Indications for use.* For the control of clinical signs associated with navicular syndrome.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 11. In § 522.812, revise paragraph (b)(2) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(2) No. 055529 for use of product described in paragraph (a)(1) as in paragraph (e)(1), and use of product described in paragraph (a)(2) as in paragraphs (e)(2)(i)(B), (e)(2)(ii)(B), (e)(2)(iii), (e)(3)(i), (e)(3)(ii)(B), and (e)(3)(iii) of this section.

* * * * *

■ 12. In § 522.814, revise paragraphs (d)(2) and (3) to read as follows:

§ 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]

BILLING CODE 4164–01–P

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