R. Gil Kerlikowske,

Commissioner, U.S. Customs and Border Protection.

Approved: October 5, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury.

[FR Doc. 2015–25729 Filed 10–9–15; 8:45 am]

BILLING CODE 9111–14–P; 9111–15–P; 9111–16–P; 9111–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 107

[Docket No. FDA–2013–N–0067]

Infant Formula: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of June 22, 2016, for the final rule that appeared in the **Federal Register** of June 23, 2015. The final rule amended the regulations on nutrient specifications and labeling for infant formula to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula.

DATES: Effective date of final rule published in the **Federal Register** of June 23, 2015 (80 FR 35834) confirmed: June 22, 2016.

FOR FURTHER INFORMATION CONTACT: Carrie Assar, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1451.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 23, 2015 (80 FR 35834), we amended the regulations on nutrient specifications and labeling for infant formula to add 2.0 µg selenium per 100 kilocalories (/100 kcal) as the minimum level of selenium in infant formulas and 7.0 µg/100 kcal as the maximum level of selenium in infant formulas.

We gave interested persons until July 23, 2015, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of June 22, 2016, should be confirmed.

List of Subjects in 21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 350a, 371) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the June 23, 2015, final rule. Accordingly, the amendments issued thereby will become effective June 22, 2016.

Dated: October 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25960 Filed 10–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 556, and 558

[Docket No. FDA–2015–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of a New Animal Drug Application; Change of Sponsor; 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 application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July and August 2015. 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 reflect a change of sponsor, a change of sponsor's address, a revised food safety warning, the voluntary withdrawal of approval of an NADA, and a technical amendment. This technical amendment is being made to improve the accuracy of the regulations.

DATES: This rule is effective October 13, 2015, except for the amendment to 21 CFR 558.460, which is effective October 23, 2015.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July and August 2015, 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.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY AND AUGUST 2015

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR sections	FOIA summary	NEPA review
141–438	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	KAVAULT (avilamycin) Type A medicated article.	Original approval for the reduction in incidence and overall severity of diarrhea in the presence of pathogenic *Escherichia coli* in groups of weaned pigs.	556.68 558.4 558.68	yes	EA/FONSI.[1]
141–442	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LUTALYSE HighCon (dinoprost tromethamine injection) Injection.	Original approval of a higher concentration formulation.	522.690	yes	CE.[2 4]
141–443	Novartis Animal Health US, Inc., 3200 Northline Ave., Suite 300, Greensboro, NC 27408.	ONSIOR (robenacoxib) Injection	Original approval for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats.	522.2075	yes	CE.[2 3]
065–252[5]	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str.,1113 Sophia, Bulgaria.	STREP–SOL (streptomycin sulfate) Solution 25%.	Supplemental approval to change marketing status from over-the-counter to by veterinary prescription.	520.2158	no	CE.[2 3]
200–553	Akorn Animal Health, Inc., 1925 West Field Ct., Suite 300, Lake Forest, IL 60045.	Neomycin and Polymyxin B Sulfates, Bacitracin Zinc Ophthalmic Ointment, USP.	Original approval as a generic copy of NADA 065–485.	524.154	yes	CE.[2 4]
200–565	Putney, Inc., One Monument Sq., Suite 400, Portland, ME 04101.	Thiabendazole, Dexamethasone, Neomycin Sulfate Solution.	Original approval as a generic copy of NADA 042–633.	524.1484g	yes	CE.[2 4]
200–582	Orkeo USA, Inc., 77 Water St., New York, NY 10005.	LONCOR 300 (florfenicol) Injectable Solution.	Original approval as a generic copy of NADA 141–063.	522.955	yes	CE.[2 4]
200–583	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	ACTOGAIN 45 (ractopamine hydrochloride) plus RUMENSIN (monensin USP) plus TYLOVET 100 (tylosin phosphate) plus MGA (melengestrol acetate) Type C medicated feeds.	Original approval as a generic copy of NADA 141–233.	558.500	yes	CE.[2 4]
200–584	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	ENGAIN 9 or 45 (ractopamine hydrochloride) plus TYLOVET 100 (tylosin phosphate) Type B and Type C medicated feeds.	Original approval as a generic copy of NADA 141–172.	558.500	yes	CE.[2 4]
200–585	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	ACTOGAIN 45 (ractopamine hydrochloride) plus RUMENSIN (monensin USP) plus TYLOVET 100 (tylosin phosphate) Type B and Type C medicated feeds.	Original approval as a generic copy of NADA 141–224.	558.500	yes	CE.[2 4]
200–591	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	NORFENICOL (florfenicol) Injectable Solution.	Original approval as a generic copy of NADA 141–063.	522.955	yes	CE.[2 4]
141–216	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	QUEST PLUS Gel (moxidectin/praziquantel)	Supplemental approval for use in breeding, pregnant, and lactating mares.	520.1453[6]	yes	CE.[2 3]
200–495	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	ENROFLOX 100 (enrofloxacin) Injectable Solution.	Supplemental approval of single-dose indications in cattle.	522.812	yes	CE.[2 4]
200–509	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	TILMOVET 90 (tilmicosin phosphate) Type A medicated article.	Supplemental approval for use of Type C medicated feeds for control of bovine respiratory disease (BRD) in groups of beef and non-lactating dairy cattle.	558.618	yes	CE.[2 4]

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

[2] The Agency has determined 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 have a significant effect on the human environment.

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

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

[5] This NADA was listed as being affected by 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.

[6] This supplemental approval required no change to the regulation.

In addition, IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200–366 for NOVOCOX (carprofen sodium) Caplets to Putney, Inc., One Monument Square, suite 400, Portland, ME 04101.

File No.	Product name	21 CFR section
200–366	NOVOCOX (carprofen sodium) Caplets	520.304

Also, Pharmgate LLC, 161 North Franklin Turnpike, suite 2C, Ramsey, NJ 07446, has informed FDA that it has changed its address to 1015 Ashes Dr., suite 102, Wilmington, NC 28405. Accordingly, 21 CFR 510.600 is being amended to reflect this change.

In addition, FDA is revising a human food safety warning for use of sulfamethazine soluble powder in pre-ruminating calves. FDA is also changing the drug labeler code for a generic dinoprost injection product in 21 CFR 522.690, which in error was omitted from a final rule changing sponsorship of an application (78 FR 17595, March 22, 2013). Also, the strength of lufenuron injectable suspension is also being amended to conform to the approved application. These technical amendments are being made to improve the accuracy of the regulations.

In addition, Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of NADA 046–666 that provides for use of Type A medicated articles containing penicillin G procaine to manufacture medicated feeds administered to poultry and swine. This action is being taken at the sponsor's request because this product is no longer manufactured or marketed. Note this NADA 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 gave notice that approval of NADA 046–666, and all supplements and amendments thereto, is withdrawn, effective October 23, 2015. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect this voluntary withdrawal of approval.

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

21 CFR Part 510

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

21 CFR Parts 520, 522, and 524

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, 524, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 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), add an entry for ''Orkeo USA, Inc.'' in alphabetical order and revise the entry for ''Pharmgate LLC''; and in the table in paragraph (c)(2), revise the entry for ''069254'' and add in numerical order an entry for ''086050'' 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
* * * * * * *	
Orkeo USA, Inc., 77 Water St., New York, NY 10005	086050
* * * * * * *	
Pharmgate LLC, 1015 Ashes Dr., Suite 102, Wilmington, NC 28405	069254
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
069254	Pharmgate LLC, 1015 Ashes Dr., Suite 102, Wilmington, NC 28405.
* * * * * * *	
086050	Orkeo USA, Inc., 77 Water St., New York, NY 10005.

Drug labeler code	Firm name and address
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.304 [Amended]

■ 4. In § 520.304, in paragraph (b)(2), remove ''000115'' and in numerical sequence add ''026637''.

■ 5. In § 520.2158, revise paragraphs (d)(1) and (2) and add paragraph (d)(3) to read as follows:

§ 520.2158 Streptomycin.

* * * * *

(d) * * *

(1) *Calves*—(i) *Amount.* 10 to 15 milligrams per pound (mg/pound) of body weight (1.0 to 1.5 grams per gallon) for up to 5 days.

(ii) *Indications for use.* For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin.

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

(2) *Swine*—(i) *Amount.* 10 to 15 mg/pound of body weight (1.0 to 1.5 grams per gallon) for up to 4 days.

(ii) *Indications for use.* For the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella* spp. susceptible to streptomycin.

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

(3) *Chickens*—(i) *Amount.* 10 to 15 mg/pound of body weight (0.6 to 0.9 grams per gallon) for up to 5 days.

(ii) *Indications for use.* For the treatment of nonspecific infectious enteritis caused by organisms susceptible to streptomycin.

(iii) *Limitations.* Withdraw 4 days before slaughter. Do not administer to chickens producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 6. In § 520.2261b, in paragraph (d)(4)(iii), revise the last two sentences to read as follows:

§ 520.2261b Sulfamethazine powder.

* * * * *

(d) * * *

(4) * * *

(iii) * * * Do not use in calves under one (1) month of age or calves being fed an all-milk diet. Use in these classes of calves may cause violative residues to remain beyond the withdrawal time.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 7. The authority citation for part 522 continues to read as follows:

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

■ 8. Amend § 522.690 as follows:

■ a. Revise paragraphs (a), (b), and (c);

■ b. Redesignate paragraphs (d)(1) and (2) as paragraphs (d)(2) and (4), respectively, and add new paragraph (d)(1);

■ c. In newly redesignated paragraph (d)(2)(ii) and in paragraph (d)(3)(ii), revise the paragraph heading ''*Indications*'', to read ''*Indications for use*''; and

■ d. Revise newly redesignated paragraph (d)(4) introductory text.

The revisions and addition read as follows:

§ 522.690 Dinoprost.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to 5 milligrams (mg) or 12.5 mg dinoprost.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 054771 for use of the 12.5 mg/mL product as in paragraph (d)(1) of this section.

(2) Nos. 000859 and 054771 for use of the 5 mg/mL product as in paragraphs (d)(2), (d)(3), and (d)(4) of this section.

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

(d) * * *

(1) *Cattle.* Administer product described in paragraph (b)(1) of this section as follows:

(i) *Amount.* 25 mg as a single intramuscular injection.

(ii) *Indications for use.* As a luteolytic agent; effective only in those cattle having a corpus luteum, *i.e.,* those which ovulated at least 5 days prior to treatment.

(A) For estrus synchronization in beef cows, beef heifers and replacement dairy heifers.

(B) For unobserved (silent) estrus in lactating dairy cows with a corpus luteum.

(C) For treatment of pyometra (chronic endometritis) in cattle.

(D) For abortion in beef cows, beef heifers and replacement dairy heifers.

(E) For use with gonadorelin injection as in § 522.1077 of this chapter to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows.

(F) For use with progesterone intravaginal inserts as in § 529.1940 of this chapter for synchronization of estrus in lactating dairy cows.

(G) For use with progesterone intravaginal inserts as in § 529.1940 of this chapter for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers.

* * * * *

(4) *Cattle.* Administer product described in paragraph (b)(2) of this section as follows:

* * * * *

■ 9. 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) of this section as in paragraph (e)(1) of this section, and use of product described in paragraph (a)(2) in this section as in paragraphs (e)(2), (e)(3)(i)(B), and (e)(3)(ii) of this section.

* * * * *

■ 10. In § 522.955, revise paragraphs (a), (b), (d)(1) subject heading, (d)(1)(i) introductory text, (d)(1)(i)(C), (d)(1)(ii) introductory text, and (d)(1)(ii)(C) to read as follows:

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter of solution contains:

(1) 300 milligrams (mg) florfenicol in the inactive vehicles 2-pyrrolidone and triacetin.

(2) 300 mg florfenicol in the inactive vehicles n-methyl-2-pyrrolidone, propylene glycol, and polyethylene glycol.

(3) 300 mg florfenicol in the inactive vehicles 2-pyrrolidone and glycerol formal.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 000061 for use of product described in paragraph (a)(1) as in paragraph (d)(1)(i); and

(2) Nos. 000061 and 086050 for use of product described in paragraph (a)(2) as in paragraph (d)(1)(ii).

(3) No. 055529 for use of product described in paragraph (a)(3) as in paragraph (d)(1)(ii).

* * * * *

(d) * * *

(1) *Beef and non-lactating dairy cattle*—(i) 300 mg per milliliter (mL) florfenicol in the inactive vehicles 2-pyrrolidone and triacetin:

* * * * *

(C) *Limitations.* Animals intended for human consumption must not be slaughtered within 44 days of treatment. Do not use in female dairy cattle 20 months of age or older. Use of florfenicol in this class of cattle may cause milk residues. A withdrawal period has not been established in pre-ruminating 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.

(ii) 300 mg/mL florfenicol in the inactive vehicles n-methyl-2-pyrrolidone, propylene glycol, and polyethylene glycol, or in 2-pyrrolidone and glycerol formal:

(C) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. Animals intended for human consumption must not be slaughtered within 33 days of subcutaneous treatment. This 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 in pre-ruminating 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.

* * * * *

§ 522.1289 [Amended]

■ 11. In § 522.1289, in paragraph (a),, remove ''10 milligrams'' and in its place add ''100 milligrams''.

■ 12. Add § 522.2075 to read as follows:

§ 522.2075 Robenacoxib.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) robenacoxib.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer 0.91 mg per pound (2 mg/kilogram) by subcutaneous injection, once daily, for a maximum of 3 days.

(2) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats at least 4 months of age for a maximum of 3 days.

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

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 13. The authority citation for part 524 continues to read as follows:

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

■ 14. In § 524.154, revise paragraphs (a)(1) and (2) and (b)(2) to read as follows:

§ 524.154 Bacitracin, neomycin, and polymyxin B ophthalmic ointment.

(a) * * *

(1) 500 units bacitracin, 3.5 milligrams (mg) neomycin sulfate (equivalent to 3.5 mg neomycin base), and 10,000 units polymyxin B sulfate; or

(2) 400 units bacitracin zinc, 5 mg neomycin sulfate (equivalent to 3.5 mg neomycin base), and 10,000 units polymyxin B sulfate.

(b) * * *

(2) Nos. 000061, 043264, and 059399 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

* * * * *

■ 15. In § 524.1484g, revise paragraphs (a) and (b) to read as follows:

§ 524.1484g Neomycin, thiabendazole, and dexamethasone solution.

(a) *Specifications.* Each milliliter of solution contains 40 milligrams (mg) thiabendazole, 3.2 mg neomycin (from neomycin sulfate), and 1 mg dexamethasone.

(b) *Sponsors.* See Nos. 026637 and 050604 in § 510.600(c) of this chapter.

* * * * *

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

■ 16. The authority citation for part 556 continues to read as follows:

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

■ 17. Add § 556.68 to read as follows:

§ 556.68 Avilamycin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of avilamycin is 1.1 milligram per kilogram of body weight per day.

(b) *Tolerances.* A tolerance for avilamycin is not required.

(c) *Related conditions of use.* See § 558.68 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 18. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 19. In § 558.4, in paragraph (d), in the ''Category I'' table, add an entry in alphabetical order for ''Avilamycin'' to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY I

Drug	Assay limits percent [1] Type A	Type B maximum (200x)	Assay limits percent Type B/C
*	*	*	*
Avilamycin	90–110	3.65 g/lb (0.8%)	80–110
*	*	*	*

* * * * *

■ 20. Add § 558.68 to read as follows:

§ 558.68 Avilamycin.

(a) *Specifications.* Each pound of Type A medicated article contains 90.7 grams of avilamycin.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Special considerations*—(1) Federal law restricts avilamycin

medicated feeds to use under a veterinary feed directive (VFD) and the professional supervision of a licensed veterinarian. See § 558.6 of this chapter for additional requirements.

(2) The expiration date of VFDs for avilamycin medicated feeds must not exceed 90 days from the date of issuance. VFDs for avilamycin shall not be refilled.

(d) *Related tolerances.* See § 556.68 of this chapter.

(e) *Conditions of use in swine*—(1) *Amount.* Feed at 73 grams avilamycin per ton of Type C medicated feed (80 ppm) as the sole ration for 21 consecutive days. The veterinarian may direct feeding for up to a total of 42 consecutive days, based on the clinical assessment.

(2) *Indications for use.* Weaned pigs less than 14 weeks of age: For the reduction in incidence and overall severity of diarrhea in the presence of pathogenic *Escherichia coli* in groups of weaned pigs.

(3) *Limitations.* Feed continuously as the sole ration.

§ 558.460 [Amended]

■ 21. In § 558.460, revise paragraphs (a) and (b) to read as follows:

§ 558.460 Penicillin.

(a) *Specifications.* Type A medicated articles containing 100 or 227 grams penicillin procaine G or feed grade penicillin procaine per pound.

(b) *Sponsor:* See No. 066104 in § 510.600(c) of this chapter.

* * * * *

§ 558.500 [Amended]

■ 22. Amend § 558.500 as follows:

■ a. In paragraphs (e)(1)(ii), (iii), and (iv), in the ''Limitations'' column, remove the last sentence and in its place add ''Ractopamine as provided by Nos. 000986 or 054771; tylosin as provided by Nos. 000986 or 016592 in § 510.600(c) of this chapter.''.

■ b. In paragraphs (e)(2)(iv), (ix), and (xiii), in the ''Limitations'' column, remove the last sentence and in its place add ''Ractopamine as provided by Nos. 000986 or 054771 with monensin as provided by No. 000986, and tylosin as provided by Nos. 000986 or 016592 in § 510.600(c) of this chapter.''.

■ c. In paragraph (e)(2)(x), in the ''Limitations'' column, to the last sentence add ''; or ractopamine as provided by No. 054771 with monensin as provided by No. 000986, tylosin provided by No. 016592, and melengestrol acetate provided by No. 054771 in § 510.600(c) of this chapter.''

§ 558.618 [Amended]

■ 23. In § 558.618, in paragraph (e)(2)(i), in the ''Sponsor'' column, add ''016592'' after ''000986''.

Dated: October 6, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–25918 Filed 10–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2015–N–0002]

New Animal Drugs for Use in Animal Feed; Withdrawal of Approval of a New Animal Drug Application; Penicillin G Procaine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) providing for the use of penicillin G procaine in medicated feed of poultry and swine. This action is being taken at the sponsor's request because this product is no longer manufactured or marketed.

DATES: Withdrawal of approval is effective October 23, 2015.

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: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of NADA 046–666 that provides for use of Type A medicated articles containing penicillin G procaine to manufacture medicated feeds administered to poultry and swine. This action is being taken at the sponsor's request because this product is no longer manufactured or marketed. Note this NADA was identified as being affected by guidance for industry #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.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to 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 NADA 046–666, and all supplements and amendments thereto, is hereby withdrawn, effective October 23, 2015.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: October 6, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–25919 Filed 10–9–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2012–N–0378]

Physical Medicine Devices; Reclassification of Shortwave Diathermy for All Other Uses, Henceforth To Be Known as Nonthermal Shortwave Therapy

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order; technical correction.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify shortwave diathermy (SWD) for all other uses, a preamendments class III device, into class II (special controls), and to rename the device ''nonthermal shortwave therapy'' (SWT). FDA is also making a technical correction in the regulation for the carrier frequency for SWD and SWT devices.

DATES: This order is effective on October 13, 2015. See further discussion in Section IV, ''Implementation Strategy.''

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993, 301–796–6283, *michael.ryan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and