

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]

BILLING CODE 4164–01–P

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