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penicillin for the production indications of growth promotion and increased feed efficiency in swine are hereby withdrawn, effective July 2, 2014.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]

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]

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.

(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.

[FR Doc. 2014–15274 Filed 6–30–14; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–351]

Schedules of Controlled Substances: Placement of Tramadol Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration places the substance 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol (tramadol), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle tramadol.

DATES: Effective August 18, 2014.

FOR FURTHER INFORMATION CONTACT: Erika Gehrmann, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, but they are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purposes of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified in one of five schedules based upon its potential for abuse, currently accepted medical use, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed * * *.'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, 28 CFR 0.100, who in turn has redelegated that authority to the Deputy Administrator of the DEA, 28 CFR part 0, appendix to subpart R.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated by four petitions to schedule tramadol under the CSA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary of the HHS and an evaluation of all relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle or propose to handle tramadol.[2]

Background

Tramadol is a centrally acting opioid analgesic that produces its primary opioid-like action through an active metabolite, referred to as the ''M1'' metabolite (O-desmethyltramadol). It was first approved for use in the United States by the U.S. Food and Drug Administration (FDA) in 1995 under the trade name ULTRAM®. Subsequently, the FDA approved for marketing generic, combination, and extended release tramadol products.

Because of its chemical structure, 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol can exist as different isomeric forms. Thus, various prefixes can be associated with the name. Some examples of these prefixes include *dextro, levo, d, l, R, S, cis, trans, erythro, threo,* (+), (−), racemic, and may include combinations of these prefixes sometimes with numerical designations. Any such isomer is, in fact, 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol. Tramadol is typically formulated as a racemic mixture identified as (±)-*cis*-2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol hydrochloride.[3]

HHS and DEA Eight-Factor Analyses

On September 16, 2010, the Assistant Secretary of the HHS provided to the DEA a scientific and medical evaluation and scheduling recommendation entitled ''Basis for the Recommendation to Schedule Tramadol in Schedule IV of the Controlled Substances Act.'' After considering the eight factors in 21

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

[2] *See* infra note 3.

[3] For simplicity, from this point forward in the document, ''tramadol'' is used to refer to 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms.