This document is scheduled to be published in the Federal Register on 03/20/2014 and available online at **http://federalregister.gov/a/2014-05882**, and on **FDsys.gov**

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2014-N-0002]

Zoetis Inc., Withdrawal of Approval of New Animal Drug Applications; Chlortetracycline; Sulfathiazole; Penicillin

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 a new animal drug application (NADA) and two abbreviated new animal drug applications (ANADAs) for three-way, fixed-ratio combination drug Type A medicated articles containing chlortetracycline, sulfathiazole, and penicillin. This action is being taken at the sponsor's request because these products are no longer manufactured or marketed.

DATES: This rule is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following NADA and two ANADAs because the products are no longer manufactured or marketed:

NADA/ ANADA	Proprietary Name
039-077	CSP 250 (chlortetracycline, sulfathiazole, and penicillin) Type A medicated article
200-140	AUREOZOL (chlortetracycline, sulfathiazole, and penicillin) Type A medicated article
200-167	AUREOZOL 500 Granular (chlortetracycline, sulfathiazole, and penicillin) Type A medicated article

The NADAs listed were 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notice that approval of NADA 039-077, ANADA 200-140, and ANADA 200-167, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals 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 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 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.

§ 558.4 [Amended]

2. In § 558.4(d), in the "Category II" table, remove the entry for "Sulfathiazole" and its respective following entries.

§ 558.155 [Removed]

3. Remove § 558.155.

Dated: March 12, 2014.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2014-05882 Filed 03/19/2014 at 8:45 am; Publication Date: 03/20/2014]