combat zone (as defined in § 416.1160(d)).

* * * * *

[FR Doc. 2010–3383 Filed 2–19–10; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2010–N–0002]

New Animal Drugs for Use in Animal Feeds; Bacitracin Zinc; Nicarbazin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) filed by Alpharma, Inc. The ANADA provides for use of single-ingredient Type A medicated articles containing bacitracin zinc and nicarbazin to make two-way combination drug Type C medicated feeds for broiler chickens.

DATES: This rule is effective February 22, 2010.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., 440 Rte. 22, Bridgewater, NJ 08807, filed ANADA 200–478 for use of ALBAC 50 (bacitracin zinc) and NICARB (nicarbazin) single-ingredient Type A medicated articles to make two-way combination drug Type C medicated feeds for broiler chickens. Alpharma, Inc.'s, ANADA 200–478 is approved as a generic copy of NADA 141–146, sponsored by Phibro Animal Health, for combination use of BACIFERM (bacitracin zinc) and NICARB. The application is approved as of January 21, 2010, and the regulations are amended in 21 CFR 558.366 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application 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.

The agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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.

§ 558.366 [Amended]

■ 2. In § 558.366, in the table in paragraph (d), in the "Nicarbazin in grams per ton" column, in the entry for "113.5 (0.0125 pct.)" under the "Combination in grams per ton" column, in the entry for "Bacitracin zinc 4 to 50," add "046573" in numeral sequence under the "Sponsor" column.

Dated: February 17, 2010.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2010–3328 Filed 2–19–10; 8:45 am]

BILLING CODE 4160–01–S