prescription for the control of inflammation in horses and cattle. Cross Vetpharm Group's Flunixin Injectable Solution is approved as a generic copy of Schering-Plough Animal Health's BANAMINE (flunixin) Solution, approved under NADA 101–479. The ANADA is approved as of March 2, 2006, and the regulations in 21 CFR 522.970 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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(a)(1) 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 522

Animal drugs.

■ 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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.970 [Amended]

■ 2. Section 522.970 is amended in paragraphs (b)(2) and (e)(2)(iii) by removing ''and 059130'' and by adding in its place ''059130, and 061623''.

Dated: March 13, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 06–3118 Filed 3–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. 2003N–0324]

New Animal Drugs for Use in Animal Feeds; Bacitracin; Nitarsone; Zoalene

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 three supplemental new animal drug applications (NADAs) filed by Alpharma, Inc. Two of the supplemental NADAs provide for the use of approved, single-ingredient Type A medicated articles containing bacitracin methylene disalicylate and zoalene, with or without roxarsone, to formulate two-way or three-way combination drug Type C medicated feeds for replacement chickens. The third NADA provides for the use of bacitracin zinc and nitarsone single-ingredient Type A medicated articles for two-way combination Type C medicated feeds for growing turkeys. These approvals reflect FDA's effectiveness conclusions, which relied on the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group's evaluation of the effectiveness of these drugs when used in animal feed as single ingredients.

DATES: This rule is effective March 31, 2006.

FOR FURTHER INFORMATION CONTACT: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV–50), 7519 Standish Pl., Rockville, MD 20855, 240–276–9090, e-mail: *andrew.beaulieu@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 8, 2003 (68 FR 47332), as corrected October 7, 2003 (68 FR 57911), as part of the Drug Efficacy Study Implementation (DESI) program CVM announced the effective conditions of use for several drug products and use combinations listed in 21 CFR 558.15. CVM proposed to withdraw the NADAs for those products or use combinations lacking substantial evidence of effectiveness following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. Alpharma, Inc., One Executive Dr., Fort Lee, NJ 07024, filed supplements to three of its approved NADAs to revise the labeling of its products to comply with these findings of effectiveness.

Alpharma, Inc., filed a supplement to approved NADA 141–130 for use of bacitracin methylene disalicylate and zoalene Type A medicated articles to formulate two-way combination drug Type C medicated feeds. This supplemental NADA provides for the use of combination feeds containing BMD (bacitracin methylene disalicylate) at 4 to 50 grams per ton (g/ton) and ZOAMIX (zoalene) at 36.3 to 113.5 g/ton of feed in replacement chickens for increased rate of weight gain and improved feed efficiency; and for development of active immunity to coccidiosis.

Alpharma, Inc., also filed a supplement to approved NADA 141–131 for use of bacitracin methylene disalicylate, zoalene, and roxarsone single-ingredient Type A medicated articles to make three-way combination drug Type C medicated feeds. This supplemental NADA provides for the use of combination feeds containing BMD (bacitracin methylene disalicylate) at 4 to 50 g/ton, ZOAMIX (zoalene) at 36.3 to 113.5 g/ton, and 3–NITRO (roxarsone) at 22.7 to 45.4 g/ton of feed in replacement chickens for increased rate of weight gain and improved feed efficiency; for development of active immunity to coccidiosis; and for improved pigmentation.

Alpharma, Inc., also filed a supplement to approved NADA 141–132 for use of bacitracin zinc and nitarsone single-ingredient Type A medicated articles to make two-way combination drug Type C medicated feeds. This supplemental NADA provides for the use of combination feeds containing ALBAC (bacitracin zinc) at 4 to 50 g/ton and HISTOSTAT (nitarsone) at 170 g/ton (0.01875 percent) of feed in growing turkeys for increased rate of weight gain and improved feed efficiency; and as an aid in the prevention of blackhead.

The DESI evaluation is concerned only with the effectiveness of the drug products and use combinations. Nothing in this document constitutes a bar to further proceedings with respect to questions of safety of the subject drugs in treated animals or of the drugs or their metabolites in food products derived from treated animals.

Products that comply with FDA's findings of effectiveness are eligible for copying as described in the *Generic Animal Drug and Patent Term Restoration Act Policy Letter Eight*, August 21, 1991 (56 FR 41561). Accordingly, sponsors may now obtain approval of abbreviated NADAs for

these three combination drug medicated feeds.

The NADAs are approved as of February 15, 2006, and the regulations are amended in 21 CFR 558.76, 558.78, 558.369, and 558.680 to reflect the approval. Approval of these supplemental NADAs did not require review of any new safety or effectiveness data. Therefore, a freedom of information summary was not prepared.

The agency has determined under 21 CFR 25.33(a)(2) that these actions are of a type that do 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.

§ 558.76 [Amended]

■ 2. In § 558.76, amend paragraph (d)(3)(xviii) by adding ''or roxarsone'' after ''arsanilic acid''.

■ 3. In § 558.78, amend paragraph (d)(3) by redesignating paragraphs (d)(3)(x) through (d)(3)(xii) as paragraphs (d)(3)(xi) through (d)(3)(xiii); and add new paragraph (d)(3)(x) to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

(d) * * *

(3) * * *

(x) Nitarsone as in § 558.369.

* * * * *

§ 558.369 [Amended]

■ 4. In § 558.369, amend paragraph (d)(2)(i) by adding ''or bacitracin zinc'' after ''disalicylate''.

■ 5. In § 558.680, amend the table in paragraph (d)(1)(i), after the entry for ''Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50'' by adding entries for ''Bacitracin 4 to 50'' and ''Bacitracin methylene disalicylate 4 to 50 plus roxarsone 22.7 to 45.4'' to read as follows:

§ 558.680 Zoalene.

* * * * *

(d) * * *

(1) * * *

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
(i) * * *	Bacitracin 4 to 50	Replacement chickens: For development of active immunity to coccidiosis; for increased rate of weight gain, improved feed efficiency	Feed as in subtable in § 558.680(d)(1)(i); grower ration not to be fed to birds over 14 weeks of age. As bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter
	Bacitracin methylene disalicylate 4 to 50 plus roxarsone 22.7 to 45.4	Replacement chickens: For development of active immunity to coccidiosis; for increased rate of weight gain, improved feed efficiency, and improved pigmentation	Feed as in subtable in § 558.680(d)(1)(i); grower ration not to be fed to birds over 14 weeks of age. Discontinue use 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. As bacitracin methylene disalicylate and roxarsone provided by No. 046573 in § 510.600(c) of this chapter
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Dated: March 22, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 06–3122 Filed 3–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. 2003N–0324]

New Animal Drugs for Use in Animal Feeds; Bacitracin; Nicarbazin; Oxytetracycline and Neomycin; 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 approval of four supplemental new animal drug applications (NADAs) filed by Phibro Animal Health. One supplemental NADA provides for the use of fixed-combination Type A medicated articles containing oxytetracycline and neomycin sulfate to formulate two-way fixed-combination drug Type B and Type C medicated feeds for chickens, turkeys, swine, cattle, and sheep. Two of the supplemental NADAs provide for the use of approved, single-ingredient Type A medicated articles containing nicarbazin and penicillin, with or without roxarsone, to formulate two-way or three-way combination drug Type C medicated feeds for broiler chickens. The fourth supplemental NADA provides for the use of approved, single-ingredient Type A medicated articles nicarbazin, bacitracin methylene disalicylate, and roxarsone to formulate three-way combination drug Type C