Dated: June 24, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–19174 Filed 7–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Flunixin Meglumine

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 a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for veterinary prescription use of flunixin meglumine solution, intravenously, for control of pyrexia associated with bovine respiratory disease and endotoxemia, and control of inflammation in endotoxemia, in beef and nonlactating dairy cattle.

EFFECTIVE DATE: July 20, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083–1982, is sponsor of NADA 101–479 Banamine® (flunixin meglumine) Injectable Solution that provides for veterinary prescription use of flunixin meglumine, intravenously or intramuscularly, for alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic in the horse. The sponsor filed a supplemental NADA that provides for veterinary prescription use of flunixin meglumine solution, intravenously, for control of pyrexia associated with bovine respiratory disease and endotoxemia, and control of inflammation in endotoxemia, in beef cattle and nonlactating dairy cattle. The supplemental NADA is approved as of May 6, 1998, and the regulations are amended in 21 CFR 522.970 by revising paragraph (b), by redesignating existing paragraph (c) as (d), by revising newly redesignated paragraph (d), and by adding paragraph (c) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, a tolerance for residues of flunixin meglumine in edible tissues of cattle has not been previously established. Section 556.286 is added to provide tolerances for flunixin meglumine residues in cattle liver (target tissue) and in cattle muscle.

Also, in addition to codifying a tolerance for flunixin residues in cattle tissues, FDA is amending the regulation to codify the acceptable daily intake (ADI) for total residues of flunixin. The ADI is the amount of total drug residue that can be consumed by humans every day. Previously, FDA had codified safe concentrations which represent the ADI corrected for consumption. The safe concentrations were confusing because few individuals understood the relationship between safe concentrations, a value representing total residues, and tolerance, the part of the drug residue in a given tissue that is detected by an analytical method. To eliminate this confusion, FDA is codifying the ADI.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval for beef cattle and nonlactating dairy cattle qualifies for 3 years of marketing exclusivity beginning May 6, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant. Three years marketing exclusivity is limited to use of the drug for the control of pyrexia associated with bovine respiratory disease and endotoxemia, and control of inflammation in endotoxemia, in beef cattle and nonlactating dairy cattle.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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 carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 522 and 556 are 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.

2. Section 522.970 is amended by revising paragraph (b), by redesignating paragraph (c) as (d), by revising newly redesignated paragraph (d), and by adding paragraph (c) to read as follows:

§ 522.970 Flunixin meglumine solution.

* * * * *

(b) *Sponsors.* See 000061 in § 510.600(c) of this chapter for use as in paragraph (d) of this section. See 000856 and 059130 for use as in paragraph (d)(1) of this section only.

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 0.5 milligram of flunixin per pound of body weight (1 milliliter per 100 pounds) per day.

(ii) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.

(iii) *Limitations.* For musculoskeletal disorders, administer intravenously or intramuscularly for up to 5 days. For colic, administer a single dose intravenously—treatment may be repeated when signs of colic recur. Caution: The effect of this drug on pregnancy has not been determined. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* 1.1 to 2.2 milligrams per kilogram of body weight (0.5 to 1 milligram per pound, 1 to 2 milliliters per 100 pounds), once a day as a single dose or divided into 2 doses administered at 12-hour intervals for up to 3 days.

(ii) *Indications for use.* For control of pyrexia associated with bovine respiratory disease and endotoxemia. Also indicated for control of inflammation in endotoxemia.

(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. Not for use in lactating or dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. Do not use in bulls intended for breeding as reproductive effects in this class of cattle have not been studied. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.286 is added to subpart B to read as follows:

§ 556.286 Flunixin meglumine.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of flunixin is 0.72 micrograms per kilogram of body weight per day.

(b) *Tolerances.* For residues of parent flunixin free acid of 0.125 part per million (ppm) in cattle liver (target tissue) and 0.025 ppm in cattle muscle are established.

Dated: July 9, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–19176 Filed 7–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Bacitracin Methylene Disalicylate and 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 a new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for using approved bacitracin methylene disalicylate and zoalene Type A medicated articles to make Type C medicated turkey feeds.

EFFECTIVE DATE: July 20, 1998.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1600.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of NADA 141–085 which provides for combining approved BMD® (10, 25, 30, 40, 50, 60, or 75 gram per pound (g/lb) bacitracin methylene disalicylate), and Zoamix® (113.5 g/lb zoalene) Type A medicated articles to make Type C medicated feeds for growing turkeys containing 4 to 50 g per ton (g/t) bacitracin methylene disalicylate and 113.5 to 170.3 g/t zoalene. The Type C medicated turkey feed is used for prevention and control of coccidiosis, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of June 3, 1998, and the regulations are amended in 21 CFR 558.76(d)(3) by adding paragraph (d)(3)(xv), and in 21 CFR 558.680(c), in the table, in item (iii) by adding an entry to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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.

FDA has determined under 21 CFR 25.33(a)(2) 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.

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.

2. Section 558.76 is amended by adding paragraph (d)(3)(xv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xv) Zoalene alone or in combination as in § 558.680.

3. Section 558.680 is amended in the table in paragraph (c)(1) in item (iii) by alphabetically adding an entry for ''Bacitracin methylene disalicylate 4–50'' to read as follows:

§ 558.680 Zoalene.

* * * * *

(c) * * *

(1) * * *

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
* *	*	*	* *
(iii) 113.5–170.3 (0.0125–0.01875%)			