(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%)			

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Bacitracin methylene disalicylate 4–50.	Turkeys; prevention and control of coccidiosis, and increased rate of weight gain and improved feed efficiency.	For turkeys grown for meat purposes only, not to be fed to laying birds, feed continuously as sole ration until 14 to 16 weeks of age.
* *	*	* *	* *

* * * * *

Dated: July 9, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–19177 Filed 7–17–98; 8:45 am]

BILLING CODE 4160–01–F

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

22 CFR Part 228

RIN 0412–AA37

Rules on Source, Origin and Nationality for Commodities and Services Financed by USAID: Miscellaneous Amendments

AGENCY: United States Agency for International Development (USAID), IDCA.

ACTION: Final rule.

SUMMARY: USAID is amending its regulation on source, origin and nationality for commodities and services financed by USAID by revising two rules, one on system determinations for commodities and one on ocean transportation eligibility, and by clarifying waiver provisions.

The final rule amends the coverage on systems determinations to allow components of a commodity system to be shipped to a cooperating country without first being shipped to and assembled in an eligible country. This should reduce the cost of these transactions by reducing unnecessary shipments. The rules on eligibility of transshipments are amended to require that suppliers obtain a determination from USAID that direct service on U.S. a flag vessel is not available before transshipment from a U.S. flag to a non-U.S. flag vessel will be eligible for USAID financing. This will ensure compliance with Cargo Preference requirements that direct U.S. flag service be used when available.

DATES: Effective September 18, 1998.

FOR FURTHER INFORMATION CONTACT: Kathleen O'Hara, Office of Procurement, Policy Division (M/OP/P) USAID, Washington, DC 20523–. Telephone: (202) 712–4759, facsimile: (202) 216–3395, e-mail address: kohara@usaid.gov.

SUPPLEMENTARY INFORMATION: The regulation at 22 CFR part 228 was published as a final rule September 15, 1996 (61 FR 53615). After operating under the regulation for a year a few areas have been identified that need some additional coverage or clarification. USAID published a proposed rule to amend 22 CFR part 228 on January 23, 1998 (63 FR 3506). The only comment received was from the American Maritime Congress which affirmed its support for the revisions to the ocean transportation eligibility policy. The rule is being amended as proposed.

List of Subjects in 22 CFR Part 228

Administrative practice and procedure, Commodity procurement, Grant programs—foreign relations.

Accordingly 22 CFR part 228 is amended as follows:

PART 228—[AMENDED]

1. The authority citation continues to read as follows:

Authority: Sec. 621, Pub. L. 87–195, 75 Stat. 445 (22 U.S.C. 2381), as amended; E.O. 12163, Sept. 29, 1979, 44 FR 56673; 3 CFR 1979 Comp., p. 435.

2. In § 228.11, paragraph (e) is revised as follows:

§ 228.11 Source and origin of commodities.

* * * * *

(e) *Systems determination.* When a system consisting of more than one produced commodity is procured as a single separately priced item, USAID may determine that the system itself shall be considered a produced commodity. When a determination is made to treat a system as a produced commodity, component commodities which originate from other than an authorized source country may be shipped directly to, and the system assembled in, the cooperating country, unless USAID specifically determines that assembly and shipment take place in an authorized source country. Transportation costs must still meet the requirements in subpart C of this part in order for them to be eligible for USAID financing. USAID, or the importer in the case of a Commodity Import Program, shall inform the supplier of any system determination.

* * * * *

3. Section 228.21 is amended by adding a sentence at the end of paragraph (a) and revising paragraph (c)(4) as follows:

§ 228.21 Ocean transportation.

(a) * * * USAID's policy on implementation of the Cargo Preference Act is in USAID's Automated Directives System, Chapter 315.

* * * * *

(c)* * *

(4) USAID will finance costs incurred on vessels under flag registry of any Geographic Code 935 country if the costs are part of the total cost on a through bill of lading that is paid to a carrier for initial carriage on a vessel which is eligible in accordance with paragraphs (c)(1), (2) or (3) of this section; provided that for shipments originating on a U.S. flag vessel with transshipment to a non-U.S. flag vessel, the supplier must obtain a determination that direct serve on a U.S. flag vessel is not available from USAID's Office of Procurement, Transportation Division, 1300 Pennsylvania Avenue NW., Washington, DC 20523–7900.

4. Section 228.51, paragraph (a) is amended by revising the introductory paragraph and paragraph (a)(1) as follows:

§ 228.51 Commodities.

(a) *Waiver criteria.* Any waiver must be based upon one of the criteria listed in this section. Waivers to Geographic Code 899 or Code 935 which are justified under paragraph (a)(2) or (3) of this section may only be authorized on a case-by-case basis. A waiver may be authorized when:

(1) A commodity required for assistance is of a type that is not produced in or available for purchase in