that residues of these compounds would be removed from the treated produce if the treatment with chlorine dioxide is followed by a potable water rinse or by blanching, cooking or canning. Therefore, the agency is including in the regulation the requirement that treatment of fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking or canning. Based on the agency's conclusions concerning this proposed use, the regulations in 21 CFR 173.300 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice. 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.

Any person who will be adversely affected by this regulation may at any time on or before August 19, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance of the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.300 is amended by revising paragraph (b) to read as follows:

§ 173.300 Chlorine dioxide.

* * * * *

(b)(1) The additive may be used as an antimicrobial agent in water used in poultry processing in an amount not to exceed 3 parts per million (ppm) residual chlorine dioxide as determined by Method 4500–ClO_2 E, referenced in paragraph (a) of this section, or an equivalent method.

(2) The additive may be used as an antimicrobial agent in water used to wash fruits and vegetables that are not raw agricultural commodities in an amount not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500–ClO_2 E, referenced in paragraph (a) of this section, or an equivalent method. Treatment of the fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking, or canning.

Dated: July 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19314 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 178

[Docket No. 97F–0405]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aluminum borate as an antistatic agent and/or antifogging agent for olefin polymers intended for use as packaging materials in contact with food. This action is in response to a petition filed by Shikoku Chemical Corp.

DATES: The regulation is effective July 20, 1998; written objections and requests for a hearing by August 19, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 25, 1997 (62 FR 50387), FDA announced that a food additive petition (FAP 7B4559) had been filed by Shikoku Chemical Corp., c/o SRS International Corp., suite 1000, 1625 K St. NW., Washington, DC 20006–1604. The petition proposed to amend the food additive regulations in § 178.3130 *Antistatic and/or antifogging agents in food-packaging materials* (21 CFR 178.3130) to provide for the safe use of aluminum borate as an antistatic and/or antifogging agent for olefin polymers complying with 21 CFR 177.1520(c) as packaging materials intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.3130 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the

documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 7B4559 (62 FR 50387, September 25, 1997). FDA has concluded that the action is of a type that does not individually or cumulatively have a significant effect on the human environment, and therefore, neither an environmental assessment nor an environmental impact statement is required.

Any person who will be adversely affected by this regulation may at any time on or before August 19, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3130 is amended in the table in paragraph (b) by alphabetically adding an entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 178.3130 Antistatic and/or antifogging agents in food-packaging materials.

* * * * *

(b) * * *

ist of substances

List of substances	Limitations
* * *	* * * *
Aluminum Borate ($(9Al_2O_3)\bullet 2(B_2O_3)$, CAS Reg. No. 11121–16–7) produced by reaction between aluminum oxide and/or aluminum hydroxide with boric acid and/or metaboric acid at temperatures in excess of 1000 °C	For use only: 1. At levels not to exceed 1 percent by weight of polypropylene films complying with § 177.1520(c) of this chapter, item 1.1, of polyethylene films complying with § 177.1520(c) of this chapter, items 2.1 and 2.2 and having a density greater than 0.94 gram per cubic centimeter, and of polyolefin copolymer films complying with § 177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.2(a), and 3.2(b). The finished polymers may be used in contact with all food types identified in Table 1 of § 176.170(c) of this chapter, under conditions of use A through H as described in Table 2 of § 176.170(c) of this chapter. The thickness of the films shall not exceed 0.005 inch. 2. At levels not to exceed 2 percent by weight of polypropylene films complying with § 177.1520(c) of this chapter, item 1.1, of polyethylene films complying with § 177.1520(c) of this chapter, items 2.1 and 2.2 and having a density greater than 0.94 gram per cubic centimeter, and of polyolefin copolymer films complying with § 177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.2(a), and 3.2(b). The finished polymers may be used in contact with all food types identified in Table 1 of § 176.170(c) of this chapter under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter. The thickness of the films shall not exceed 0.005 inch.
* * *	* * * *

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.