the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective August 19, 1977.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348 (c)(1)))

Dated: August 12, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-23981 Filed 8-18-77;8:45 am]

[Docket No. 76F-0387]

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

Components In Contact with Aqueous and Fatty Food

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the food additive regulations to provide for safe use of a chemical as a component of paper and paperboard intended for food-contact use. This amendment is based on a petition filed by Buckman Laboratories, Inc.

DATES: Effective August 19, 1977; objections by September 19, 1977.

ADDRESSES: Written objections to this regulation may be filed with the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

John J. McAuliffe, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: A notice published in the FEDERAL REGISTER of September 29, 1976 (41 FR 42970) announced that a food additive petition (FAP 6B3184) had been filed by Buckman Laboratories, Inc., 1256 North McLean Blvd., Memphis, TN 38108, proposing that § 176.170 (21 CFR 176.170, formerly § 121.2526, prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) be amended to provide for safe use of epichlorohydrin polymer with monomethylamine, reaction product with N,N,N',N'-tetramethylethylenediamine as a component of paper and paperboard intended for use in contact with aqueous and fatty foods.

The Commissioner of Food and Drugs, having evaluated data in the food additive petition and other relevant material, concludes that § 176.170 should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 176 is amended in § 176.170(a)(5) by alphabetically inserting in the list of substances a new item, to read as follows:

§ 176.170 **Components of paper and paperboard to contact with aqueous and fatty foods.**

* * * * * *

(a) * * *

(5) * * *

List of substances	*Limitations*
* * * * *	* * * * *
Polyamine-epichlorohydrin resin produced by reaction of epichlorohydrin with monomethylamine to form a prepolymer and further reaction of this prepolymer with N,N,N',N'-tetramethylethylenediamine such that the finished resin having a nitrogen content of 11.6 to 14.8 percent and a chlorine content of 20.8 to 26.4 percent and a minimum viscosity, in 25 percent by weight aqueous solution, of 500 centipoises at 25° C, as determined by LV-series Brookfield viscometer using a No. 2 spindle at 12 r.p.m. (or by other equivalent method).	For use only as a flocculant, drainage aid, formation aid, retention aid, or strength additive employed prior to the sheet-forming operation in the manufacture of paper and paperboard, and used at a level not to exceed 0.12 percent by weight of dry paper and paperboard fibers.
* * * * *	* * * * *

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before September 19, 1977 submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective August 19, 1977.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348 (c)(1)).)

Dated: August 12, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-23982 Filed 8-18-77;8:45 am]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 75F-0173]

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

Slimicides

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The food additive regulations are amended to provide for safe use of a chemical mixture as a component of slimicides in the manufacture of paper and paperboard intended to contact food. This amendment is based on evaluation of data contained in a food additive petition submitted by Rohm and Hass Co.

EFFECTIVE DATE: August 19, 1977; objections by September 19, 1977.

ADDRESS: Written objections to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

John J. McAuliffe, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: A notice published in the FEDERAL REGISTER of August 18, 1975 (40 FR 34624) announced that a food additive petition (FAP 5H3107) had been filed by Rohm and Haas Co., Independence Mall West, Philadelphia, PA 19105, proposing that §176.300 (21 CFR 176.300, formerly § 121.2505 prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)), be amended to provide for the safe use of 5-chloro-2-

methyl - 4 - isothiazolin - 3 - one calcium chloride and 2-methyl-4-isothiazolin-3-one calcium chloride as components of a slimicide in the manufacture of paper and paperboard intended to contact food.

The Commissioner of Food and Drugs, having evaluated the data in the food additive petition and other relevant material, concludes that § 176.300 should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 176 is amended in § 176.300(c) by alphabetically inserting a new item in the list of substances, to read as follows:

§ 176.300 Slimicides.

(c) * * *

List of substances	*Limitations*
* * *	* * *
5-Chloro-2 - methyl - 4 - isothiazolin-3-one calcium chloride and 2-methyl-4-isothiazolin-3-one calcium chloride mixture at a ratio of 3 parts to 1 part.	At a level of 2.5 pounds per ton of dry weight fiber.
* * *	* * *

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before September 19, 1977 submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective August 19, 1977.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)).)

Dated: August 12, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-24148 Filed 8-18-77;8:45 am]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 510—NEW ANIMAL DRUGS

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Poloxalene

AGENCY: Food and Drug Administration, HEW.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect an approved new animal drug application filed by A. E. Staley Manufacturing Co. The amendment provides for a medicated block for control of legume bloat in feeding cattle.

EFFECTIVE DATE: August 19, 1977.

FOR FURTHER INFORMATION CONTACT:

David N. Scarr, Bureau of Veterinary Medicine (HFV-214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3183.

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)), Parts 510 and 520 (21 CFR 510 and 520) are amended to reflect an approved new animal drug application (NADA 33-773V) filed by A. E. Staley Manufacturing Co., 2200 Eldorado St., Decatur, IL 62525. The regulation reflecting this approval was originally published in the FEDERAL REGISTER of March 14, 1967 (32 FR 4019). The sponsor is incorrectly listed in the current regulations.

Publication of this approval has not required a reevaluation of the parent NADA and does not constitute a reaffirmation of the drug's safety and effectiveness.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Parts 510 and 520 are amended as follows:

1. In Part 510, § 510.600 is amended in paragraph (c)(1) by adding a new sponsor alphabetically, and in paragraph (c)(2) by adding a new sponsor numerically, as follows:

§ 510.600 Names, addresses, and code numbers of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address:	*Drug listing No.*
* * * * *	
A. E. Staley Manufacturing Co., 2200 Eldorado St., Decatur, IL 62525.	012315
* * * * *	

(2) * * *

Drug listing No.:	*Firm name and address*
* * * * *	
012315	A. E. Staley Manufacturing Co., 2200 Eldorado St., Decatur, IL 62525.
* * * * *	

2. In Part 520, § 520.1840 is amended by revising paragraph (c)(2) and adding new paragraph (c)(3), to read as follows:

§ 520.1840 Poloxalene.

* * * * *

(c) * * *

(2) See No. 000007 in § 510.600(c) of this chapter for sponsor of usage provided by paragraph (d)(3) of this section.

(3) See No. 012315 in § 510.600(c) of this chapter for sponsor of usage provided by paragraph (d)(2) of this section.

* * * * *

Effective date: August 19, 1977.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: August 9, 1977.

FRED J. KINGMA,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc.77-23618 Filed 8-18-77;8:45 am]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Amprolium Crumbles

AGENCY: Food and Drug Administration, HEW.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by Merck Sharp & Dohme Research Laboratories for use of amprolium crumbles as an aid in prevention and treatment of coccidiosis in calves.

EFFECTIVE DATE: August 19, 1977.

FOR FURTHER INFORMATION CONTACT:

Adriano R. Gabuten, Bureau of Veterinary Medicine (HFV-149), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, (301-443-4913).

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the act (21 U.S.C. 360b(i)), Part 520 (21 CFR Part 520) is amended to reflect approval of a supplemental NADA (12-350V) filed by Merck Sharp & Dohme Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065. The crumbles contain 1.25 percent amprolium that is topdressed on or mixed in the daily feed ration of calves as an aid in prevention and treatment of coccidiosis.

Approval of this application has not required a reevaluation of the parent NADA and does not constitute a reaffirmation of the drug's safety and effectiveness.

In accordance with the Freedom of Information Regulations and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of the safety data and information submitted to support the approval of this

application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFC–20), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioned of Food and Drugs (21 CFR 5.1), Part 520 is amended by adding new § 520.100c Amprolium crumbles to read as follows:

§ 520.100c Amprolium crumbles.

(a) *Specifications.* Amprolium crumbles contain 1.25 percent amprolium.

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use.* It is top-dressed on or thoroughly mixed in the daily feed ration of calves as follows:

(1) *Amount.* 1.6 ounces of crumbles per 250 pounds of body weight per day (5 milligrams per kilogram of body weight).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(ii) *Limitations.* Administer for 21 consecutive days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

(2) *Amount.* 3.2 ounces of crumbles per 250 pounds of body weight per day (10 milligrams per kilogram of body weight).

(i) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(ii) *Limitations.* Administer for 5 consecutive days. For satisfactory diagnosis, a microscopic fecal examination should be done by a veterinarian or diagnostic laboratory before treatment. When treating outbreaks, the drug should be administered promptly after diagnosis is determined. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

Effective date: August 19, 1977.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: August 11, 1977.

FRED J. KINGMA,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc.77–23620 Filed 8–18–77;8:45 am]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Phenylbutazone Tablets

AGENCY: Food and Drug Administration (FDA), HEW.

ACTION: Rule.

SUMMARY: FDA approves a new animal drug application (NADA 102–823V) filed by Norden Laboratories, Inc., Lincoln, NE 68501, proposing safe and effective use of phenylbutazone tablets to treat horses for the management of inflammatory conditions associated with the musculo-skeletal system. The Commissioner of Food and Drugs is amending § 520.1720a (21 CFR 520.1720a) to reflect this approval.

DATES: Effective August 19, 1977.

FOR FURTHER INFORMATION CONTACT:

Robert A. Baldwin, Bureau of Veterinary Medicine (HFV–114), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3420.

SUPPLEMENTARY INFORMATION: In accordance with § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) of the animal drug regulations, a summary of the safety and effectiveness data and information submitted to support the approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFC–20), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, Monday through Friday from 9 a.m. to 4 p.m., except on Federal legal holidays.

Norden Laboratories, Inc., currently holds an approved NADA for use of phenylbutazone tablets for treating dogs, which is provided for in § 520.1720a(h) (21 CFR 520.1720a(h)). The firm will now have NADA approvals for use in dogs and horses. Accordingly, § 520.1720a is being amended to delete paragraph (h), which references the use for dogs only, and to insert the approvals under paragraph (g), which indicates uses for both animals.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner (21 CFR 5.1), § 520.1720a is amended by revising paragraph (g)(2) and by deleting and reserving paragraph (h) as follows:

§ 520.1720a Phenylbutazone tablets and boluses.

* * * * *

(g)(1) * * *

(2) *Sponsor.* See Nos. 000031, 000864, and 011519 in § 510.600(c) of this chapter.

* * * * *

(h) [Reserved]

* * * * *

Effective date: This regulation becomes effective August 19, 1977.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: August 9, 1977.

FRED J. KINGMA,
Acting Director, Bureau of
Veterinary Medicine.

[FR Doc.77–23617 Filed 8–18–77;8:45 am]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Disophenol Sodium Injection

AGENCY: Food and Drug Administration, HEW.

ACTION: Final rule.

SUMMARY: This document provides for safe and effective use of an injection for treating hookworm infections in dogs and cats. American Cyanamid Co. filed an application for this use. The Commissioner of the Food and Drug Administration is amending the animal drug regulations to reflect this approval.

EFFECTIVE DATE: August 19, 1977.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV–112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3430.

SUPPLEMENTARY INFORMATION: A supplemental new animal drug application (12–598V), filed by the American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540, provides for the use of a 0.9 percent disophenol sodium injection for treating hookworm infections in puppies, "toy" breeds, and cats.

In accordance with § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) of the animal drug regulations, a summary of the safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFC–20), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, during regular working hours.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)), and under authority delegated to the Commissioner (21 CFR 5.1), Part 522 is amended by revising paragraph (b) of § 522.740 to read as follows:

§ 522.740 Disophenol sodium injection.

* * * * *

(b) *Specifications.* The drug is sterile and contains the equivalent of 0.9 or 4.5 percent disophenol in polyethylene glycol 400 and distilled water.

* * * * *

Effective date: August 19, 1977.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: August 10, 1977.

FRED J. KINGMA,
Acting Director, Bureau of
Veterinary Medicine.

[FR Doc.77–23619 Filed 8–18–77;8:45 am]

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Amprolium, Ethopabate, Bacitracin Methylene Disalicylate; Correction

AGENCY: Food and Drug Administration.