

pool operators ("CPOs"). (54 FR 5597 (February 6, 1989).) The Commission requested comment on matters related to the presentation of prior performance data by CPOs and commodity trading advisors ("CTAs") and the presentation of the fees, commissions and expenses incurred by pools, and on any other issues relating to Part 4 disclosure requirements. The interpretive statement provided a period for public comment which ended April 7, 1989.

The Commission has been requested by several potential commentators to extend the comment period for the interpretive statement. Such additional time has been requested in order to allow the associations representing CPOs and CTAs to receive and analyze the comments of their memberships and present them to the Commission. The Commission believes that a thirty-day extension period is appropriate to enhance the opportunity for interested parties to comment on the issues raised in the release.

DATE: All comments on the Commission's interpretive statement concerning Part 4 disclosure requirements (54 FR 5597 (February 6, 1989)) must be received by May 5, 1989.

ADDRESS: Comments should be sent to the Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581.

FOR FURTHER INFORMATION CONTACT: Tobey W. Kaczynsky, Associate Director, Division of Trading and Markets, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Telephone (202) 254-8955.

Issued in Washington, this 13th day of April, 1989.

Lynn K. Gilbert,

Deputy Secretary to the Commission.

[FR Doc. 89-9279 Filed 4-18-89; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 88F-0177]

Indirect Food Additives; Adhesives and Components of Coatings

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polypropylene glycol

dibenzoate and propylene glycol dibenzoate as components of adhesives in contact with food. This action is in response to two petitions filed by the Velsicol Chemical Corp.

DATES: Effective April 19, 1989; written objections and requests for a hearing by May 19, 1989.

ADDRESS: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard H. White, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 22, 1988 (53 FR 23455), FDA announced that two food additive petitions (FAP 8B4070 and FAP 8B4071) had been filed by Velsicol Chemical Corp., 5600 North River Rd., Rosemont, IL 60018-5119, proposing that § 175.105 *Adhesives* (21 CFR 175.105) of the food additive regulations be amended to provide for the safe use of polypropylene glycol dibenzoate and propylene glycol dibenzoate, respectively, as components of adhesives in contact with food.

FDA has evaluated data in the petitions and other relevant material. The agency concludes that the proposed food additive uses for polypropylene glycol dibenzoate and propylene glycol dibenzoate are safe, and that § 175.105(c)(5) should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petitions and the documents that FDA considered and relied upon in reaching its decision to approve these petitions 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 21 CFR 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 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 environmental impact statements are not required. The agency's findings of no significant impact and the evidence supporting those findings, contained in the environmental assessments, 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 May 19, 1989 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.

List of Subjects in 21 CFR Part 175

Adhesives, 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, Part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR Part 175 continues to read as follows:

Authority: Sections 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 175.105 is amended in paragraph (c)(5) by alphabetically adding two new entries in the table to read as follows:

§ 175.105 Adhesives.

*	*	*	*
(c)	*	*	*
(5)	*	*	*

Substances	Limitations
Propylene glycol dibenzoate (CAS Reg. No. 72245-46-8). Propylene glycol dibenzoate (CAS Reg. No. 19224-26-1).	For use as a plasticizer at levels not to exceed 20 percent by weight of the finished adhesive. For use as a plasticizer at levels not to exceed 20 percent by weight of the finished adhesive.

Dated: April 10, 1989.

Richard J. Rork,
Acting Director, Center for Food Safety and
Applied Nutrition.
[FR Doc. 89-9270 Filed 4-18-89; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 177

[Docket No. 87F-0155]

Indirect Food Additives; Polymers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethylene terephthalate-isophthalate copolymers containing a minimum of 98 weight percent of polymer units derived from ethylene terephthalate for use as a component of articles in contact with alcoholic beverages. This action responds to a petition filed by the Goodyear Tire & Rubber Co.

DATES: April 19, 1989; objections by May 19, 1989.

ADDRESS: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 4, 1987 (52 FR 21122), FDA announced that a petition (FAP 7B3990) had been filed by the Goodyear Tire & Rubber Co., 130 Johns Ave., Akron, OH 44305-4097, proposing that § 177.1630 *Polyethylene phthalate polymers* (21 CFR 177.1630) be amended to provide for the safe use of ethylene terephthalate-isophthalate copolymers containing a minimum of 98 weight

percent of polymer units derived from ethylene terephthalate for use as a component of articles in contact with alcoholic beverages.

The agency received one comment concerning the petition. The comment was in support of the petition.

FDA has evaluated data in the petition and other relevant material, and concludes that the proposed food additive use is safe, and that § 177.1630 should be amended by adding new paragraph (j).

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 21 CFR 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 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 May 19, 1989, 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 of 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.

List of Subjects in 21 CFR Part 177

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 of the Center for Food Safety and Applied Nutrition, Part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR Part 177 continues to read as follows:

Authority: Sections 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 177.1630 is amended by adding new paragraph (j) to read as follows:

§ 177.1630 Polyethylene phthalate polymers.

(j) Polyethylene phthalate plastics, composed of ethylene terephthalate-isophthalate containing a minimum of 98 weight percent of polymer units derived from ethylene terephthalate, conforming with the specifications prescribed in paragraph (j)(1) of this section are used as provided in paragraph (j)(2) of this section.

(1) *Specifications.* (i) The food contact surface meets the specifications in paragraph (f)(1) of this section and

(ii)(a) *Containers with greater than 500 mL capacity.* The food-contact surface when exposed to 95 percent ethanol at 120° F for 24 hours should not yield chloroform-soluble extractives in excess of 0.005 mg/in².

(b) *Containers with less than or equal to 500 mL capacity.* The food contact surface when exposed to 95 percent ethanol at 120° F for 24 hours should not yield chloroform-soluble extractives in excess of 0.05 mg/in².

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding alcoholic foods that do not exceed 95 percent alcohol by volume.

Dated: April 10, 1989.

Richard J. Rork,
Acting Director, Center for Food Safety and
Applied Nutrition.
[FR Doc. 89-9271 Filed 4-18-89; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Sulfamethazine Boluses

AGENCY: Food and Drug Administration.
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 Norden Laboratories, Inc. The application provides for the use of a bolus containing 5 grams of sulfamethazine for the treatment of certain diseases in ruminating beef and dairy calves.

EFFECTIVE DATE: April 19, 1989.

FOR FURTHER INFORMATION CONTACT: Charles E. Haines, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: Norden Laboratories, Inc., Lincoln, NE 68501, has filed NADA 140-909 (formerly NADA 99-987) which provides for the use of a 5-gram sulfamethazine bolus. The drug is indicated for use in ruminating beef and dairy calves for treating bacterial scours (colibacillosis) caused by *Escherichia coli*, necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*, bacterial pneumonia associated with *Pasteurella* spp., and coccidiosis caused by *Eimeria bovis* and *Eimeria zurnii*. The NADA is approved and 21 CFR 520.2260a is amended to reflect the approval. The NADA was originally filed as NADA 99-987 and contained sulfamethazine and neomycin. Norden Laboratories, Inc., reformulated the product by removing the neomycin and FDA has renumbered the application as NADA 140-909. (The status of the product containing sulfamethazine and neomycin under the Center for Veterinary Medicine's notice of opportunity for a hearing on its proposal to refuse approval of certain sulfonamide-containing drugs (53 FR 46050; November 15, 1988, corrected December 12 and 23, 1988; 53 FR 49968 and 51950; and February 2, 1989; 54 FR 5303) will be addressed in a notice to be published in a future issue of the Federal Register.) The basis for approval of NADA 140-909 is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 520

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, Part 520 is amended as follows:

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

1. The authority citation for 21 CFR Part 520 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. Section 520.2260a is revised to read as follows:

§ 520.2260a Sulfamethazine oblets and boluses.

(a)(1) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter for use of 2.5-, 5-, or 15-gram sulfamethazine oblet.

(2) *Related tolerance in edible products.* See § 556.670 of this chapter.

(3) *Conditions of use—(i) Amount.* Administer as a single dose 100 milligrams of sulfamethazine per pound of body weight the first day and 50 milligrams per pound of body weight on each following day.

(ii) *Indications for use.* For treatment of diseases caused by organisms susceptible to sulfamethazine.

(A) *Beef cattle and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), coccidiosis (*Eimeria bovis* and *Eimeria zurnii*).

(B) *Horses.* Treatment of bacterial pneumonia (secondary infections associated with *Pasteurella* spp.), strangles (*Streptococcus equi*), and bacterial enteritis (*Escherichia coli*).

(iii) *Limitations.* Administer daily until animal's temperature and appearance are normal. If symptoms persist after using for 2 or 3 days consult a veterinarian. Fluid intake must be adequate. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed 5 consecutive days. Follow dosages carefully. Not for use in lactating dairy animals. Do not treat cattle within 10 days of slaughter. Not to be used in horses intended for food.

(4) *NAS/NRC status.* The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(b)(1) *Sponsor.* See No. 011519 in § 510.600(c) of this chapter for use of 5-gram sulfamethazine bolus.

(2) *Related tolerances in edible products.* See § 556.670 of this chapter.

(3) *Conditions of use—(i) Amount.* Administer 10 grams (2 boluses) of sulfamethazine per 100 pounds of body weight the first day, then 5 grams (1 bolus) of sulfamethazine per 100 pounds of body weight daily for up to 4 additional consecutive days.

(ii) *Indications for use.* Ruminating beef and dairy calves. For treatment of the following diseases caused by organisms susceptible to sulfamethazine: bacterial scours (colibacillosis) caused by *E. coli*; necrotic pododermatitis (foot rot) and calf diphtheria caused by *F. necrophorum*; bacterial pneumonia associated with *Pasteurella* spp.; and coccidiosis caused by *E. bovis* and *E. zurnii*.

(iii) *Limitations.* Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older; such use may cause drug residues in milk. Administer with adequate supervision. Follows recommended dosages carefully. Fluid intake must be adequate. If symptoms persist after 2 or 3 days, consult a veterinarian.

Dated: April 12, 1989.

Gerald B. Guest,

Director, Center for Veterinary Medicine.
 [FR Doc. 89-9347 Filed 4-18-89; 8:45 am]

BILLING CODE 4160-01-M