authorized installed capacity to reflect the change.

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[FR Doc. 95–28559 Filed 11–22–95; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 92F–0086]

Indirect Food Additives: Polymers

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 ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer containing up to 5 mole percent (7 weight percent) 1,4-cyclohexylene dimethylene terephthalate as a base sheet and base polymer for use in food-contact articles. This action is in response to a petition filed by Eastman Chemical Co.

DATES: Effective November 24, 1995; written objections and requests for a hearing by December 26, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Diane E. Robertson, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of April 13, 1992 (57 FR 12831), FDA announced that a food additive petition (FAP 2B4318) had been filed by Eastman Chemical Co., P.O. Box 511, Kingsport, TN 37662. The petition proposed to amend the food additive regulations to provide for the safe use of copolyesters containing up to 5 mole percent (7 weight percent) 1,4-cyclohexylene dimethylene terephthalate as the base sheet and base polymer for use in food-contact articles.

FDA has evaluated the data and information in the petition and concludes that the proposed use of the additive as a base sheet and base polymer is safe. The agency also concludes that the additive is currently regulated under § 177.1315 *Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers* (21 CFR 177.1315) and that this new use should be regulated under the same name. Further, the agency concludes that both §§ 177.1315 and 177.1630 *Polyethylene phthalate polymers* (21 CFR 177.1630) 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 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 December 26, 1995, 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 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, Center for Food Safety and Applied Nutrition, 21 CFR 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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 177.1315 is amended in the table in paragraph (b) by adding new entry ''3.'' to read as follows:

§ 177.1315 Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers.

* * * * *

(b) *Specifications*:

Ethylene 1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/ square centimeter of food-contact surface)	Test for orientability	Conditions of use
* *	*	*	*	* *
3. Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 95 mole percent of ethylene glycol and 1 to 5 mole percent of 1,4-cyclohexanedimethanol (70 percent *trans* isomer, 30 percent *cis* isomer).	No test required .	For each corresponding condition of use, must meet specifications described in § 177.1630(f), (g), (h), or (j).	No test required	For each corresponding specification, may be used as a base sheet and base polymer in accordance with conditions of use described in § 177.1630(f), (g), (h), or (j).

* * * * *

3. Section 177.1630 is amended by revising paragraphs (a), (b), and the introductory text of paragraph (j) and by amending paragraph (e)(4)(ii) by alphabetically adding a new substance to the ''List of Substances and Limitations'' to read as follows:

§ 177.1630 Polyethylene phthalate polymers.

* * * * *

(a) Polyethylene phthalate films consist of a base sheet of ethylene terephthalate polymer, ethylene terephthalate-isophthalate copolymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in § 177.1315(b)(3), to which have been added optional substances, either as constituents of the base sheet or as constituents of coatings applied to the base sheet.

(b) Polyethylene phthalate articles consist of a base polymer of ethylene terephthalate polymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in § 177.1315(b)(3), to which have been added optional substances, either as constituents of the base polymer or as constituents of coatings applied to the base polymer.

* * * * *

(e) * * *

(4) * * *

(ii) * * *

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in § 177.1315(b)(3).

* * * * *

(j) Polyethylene phthalate plastics, composed of ethylene terephthalate-isophthalate containing a minimum of 98 weight percent of polymer units derived from ethylene terephthalate, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in § 177.1315(b)(3), conforming with the specifications prescribed in paragraph (j)(1) of this section, are used as provided in paragraph (j)(2) of this section.

Dated: November 10, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–28545 Filed 11–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 310, 355, and 369

[Docket No. 80N–0042]

RIN 0910–AA01

Anticaries Drug Products for Over-The-Counter Human Use; Final Monograph; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of October 6, 1995 (60 FR 52474). The document established conditions under which over-the-counter (OTC) anticaries drug products (products that aid in the prevention of dental cavities) are generally recognized as safe and effective and not misbranded. The document was published with some errors. This document corrects those errors.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTARY INFORMATION: In FR Doc. 95–24693, appearing on page 52474 in the Federal Register of Friday, October 6, 1995, the following corrections are made:

1. On page 52484, in the first column, in the first full paragraph, beginning in the 12th line from the bottom, the phrase ''as the following: 'anticavity fluoride' (select one of the following'' is corrected to read ''as: (select one or both of the following: 'anticavity' or 'fluoride' ''.

2. On page 52504, in the table, in the entry for ''Sodium monofluorophosphate (1,500 ppm):'', the designation ''NM'' is removed. § 355.50 [Corrected]

3. One page 52508, in the third column, in § 355.50 Labeling of anticaries drug products, in paragraph (a), beginning in line 4, the phrase ''as the following: 'anticavity fluoride' (select one of the following'' is corrected to read ''as: (select one or both of the following: 'anticavity' or 'fluoride')''.

Dated: November 16, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–28600 Filed 11–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Semduramicin; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.