DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 92F–0279]

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 *N,N*-bis(2-hydroxyethyl)dodecanamide as an antistatic agent in polypropylene food-packaging films. This action responds to a petition filed by Toho Chemical Industry Co., Ltd., c/o Parexel International Corp.

DATES: Effective June 10, 1997. Written objections and requests for a hearing by July 10, 1997.

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

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 7, 1992 (57 FR 34937), FDA announced that a food additive petition (FAP 2B4308) had been filed by Toho Chemical Industry Co., Ltd., c/o Parexel International Corp., 195 West St., Waltham, MA 02154. 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 *N,N*-bis(2-hydroxyethyl)dodecanamide as an antistatic agent in polypropylene food-packaging films.

FDA has evaluated data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the food additive is safe, (2) the additive will achieve its intended technical effect, and (3) 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 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 July 10, 1997, 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 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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3130 is amended in the table in paragraph (b) by revising the entry for ''*N,N*-Bis(2-hydroxyethyl) dodecanamide * * *'' to read as follows:

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

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
N,N-Bis(2-hydroxyethyl)dodecanamide produced when diethanolamine is made to react with methyl laurate such that the finished product: Has a minimum melting point of 36 °C; has a minimum amide assay of 90 percent; contains no more than 2 percent by weight of free diethanolamine; and contains no more than 0.5 percent by weight of *N,N,* bis(2-hydroxyethyl)piperazine, as determined by paper chromatography method.	For use only: 1. As an antistatic agent at levels not to exceed 0.5 percent by weight of molded or extruded polyethylene containers intended for contact with honey, chocolate syrup, liquid sweeteners, condiments, flavor extracts and liquid flavor concentrates, grated cheese, light and heavy cream, yogurt, and foods of Type VIII as described in Table 1 of § 176.170(c) of this chapter. 2. As an antistatic agent at levels not to exceed 0.2 percent by weight in polypropylene films complying with § 177.1520 of this chapter, and used in contact with food of Types I, II, III, IV, V, VI–B, VII, VIII, and IX described in Table 1 of § 176.170(c) of this chapter, and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. The average thickness of such polypropylene film shall not exceed 0.001 inches (30 micrometers).
* * *	* * * *

Dated: May 23, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–15011 Filed 6–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 95N–0033]

Dental Devices; Endodontic Dry Heat Sterilizer; Corrections and Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; corrections and technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of January 21, 1997 (62 FR 2900). The document issued a final rule to require the filing of a premarket approval application or a notice of completion of a product development protocol for the endodontic dry heat sterilizer, a medical device. The document was published with some errors. This document corrects those errors.

EFFECTIVE DATE: January 21, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

The Corrections

In FR Doc. 97–1336, beginning on page 2900 in the **Federal Register** of Tuesday, January 21, 1997, the following corrections are made:

1. On page 2900, in the third column, in the second full paragraph, in the thirty-first line, ''September 5, 1995'' is corrected to read ''June 22, 1995'' and on that same page, in the third column, in the second full paragraph, in the thirty-second line, ''August 7, 1995'' is corrected to read ''September 5, 1995''.

2. On page 2902, in the second column, in the second paragraph, in the fourth line, and on that same page, in the second column, in the third paragraph, in the twenty-second line, ''September 5, 1995'' is corrected to read ''April 21, 1997''.

3. On page 2902, in the second column, in the third paragraph, in the twenty-eighth line, ''August 7, 1995'' is corrected to read ''March 21, 1997.''

The Technical Amendment

§ 872.6730 [Amended]

4. Section 872.6730 *Endodontic dry heat sterilizer* is amended in paragraph (c) by removing ''September 5, 1995'' each time it appears and adding in its place ''April 21, 1997''.

Dated: May 27, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiologica Health.

[FR Doc. 97–15013 Filed 6–9–97; 8:45 am]

BILLING CODE 4160–01–F

POSTAL SERVICE

39 CFR Part 111

Special Services Reform; Implementation Standards

AGENCY: Postal Service.

ACTION: Supplementary final rule.

SUMMARY: This supplementary final rule sets forth the remaining Domestic Mail Manual (DMM) standards adopted by the Postal Service to implement the Decision of the Governors of the United States Postal Service on the Recommended Decision of the Postal Rate Commission on Special Services and Fees, Docket No. MC96–3. These standards constitute only minor changes or refinements to internal operational procedures that have been made since publication of the final rule in the **Federal Register** on May 12, 1997 (62 FR 26086–26099).

The standards in this supplementary final rule do not, in any way, affect the fees or attributes of the special services as they were published in the final rule for post office box service and caller service, certified mail, insurance (insured mail and Express Mail), parcel airlift, registered mail, return receipt service, return receipt for merchandise service, and stamped cards (formerly named postal cards). Although no substantive changes have been made to the final rule, this supplementary final rule does respond to comments that the Postal Service had sought with publication of the final rule.

EFFECTIVE DATE: June 8, 1997.

FOR FURTHER INFORMATION CONTACT: Neil Berger, (202) 268–2859.

SUPPLEMENTARY INFORMATION: On June 7, 1996, pursuant to its authority under 39 U.S.C. 3621, et seq., the Postal Service filed with the Postal Rate Commission (PRC) a request for a recommended decision on several special service reform proposals. The PRC designated the filing as Docket No. MC96–3. The PRC published a notice of the filing, with a description of the Postal Service's proposals, on June 21, 1996, in the **Federal Register** (61 FR 31968–31979).

Pursuant to 39 U.S.C. 3624, on April 2, 1997, the PRC issued its