be used as the book cost of the units retired

\* \* \* \* \*

- 7. In Part 201, Gas Plant Instruction 11, paragraph C is revised to read as follows:
- 11. Work Order and Property Record System Required.

\* \* \* \* \*

C. Each utility shall maintain records in which, for each plant account, the amounts of the annual additions and retirements are classified so as to show the number and cost of the various record units or retirement units.

#### PART 216—UNITS OF PROPERTY FOR USE IN ACCOUNTING FOR ADDITIONS TO AND RETIREMENTS OF GAS PLANT

8. Part 216 is removed.

### PART 352—UNIFORM SYSTEM OF ACCOUNTS PRESCRIBED FOR OIL PIPELINE COMPANIES SUBJECT TO THE PROVISIONS OF THE INTERSTATE COMMERCE ACT

9. The authority citation for Part 352 continues to read as follows:

**Authority:** 49 U.S.C. 60502, 49 App. U.S.C. 1–85

- 10. In Part 352, Instructions for Carrier Property Accounts, instruction 3–2, Minimum rule is removed. In instructions 3–5, introductory text, and 3–6(a) the phrase "subject to the minimum rule" is removed.
- 11. In Part 352, Instructions for Carrier Property Accounts, instruction 3–4 *Additions* is revised to read as follows:
- 3–4 Additions. Each carrier shall maintain a written property units listing for use in accounting for additions and retirements of carrier plant and apply the listing consistently. When property units are added to Carrier plant, the cost thereof shall be added to the appropriate carrier plant account as set forth in the policy.
- 12. In Part 352, Instructions for Carrier Property Accounts, instruction 3–7 *Retirements* introductory text and paragraph (b)(1) are revised and new paragraph (c) is added to read as follows:
- 3–7 Retirements. When property units are retired from carrier plant, with or without replacement, the cost thereof and the cost of minor items of property retired and not replaced shall be credited to the carrier plant account in which it is included. The retirement of carrier property shall be accounted for as follows:

(a) \* \* \*

(b) Property. (1) The book cost, as set forth in paragraph c below, of units of property retired and of minor items of property retired and not replaced shall be written out of the property account as of date of retirement, and the service value shall be charged to account 31, Accrued Depreciation—Carrier Property.

\* \* \* \* \*

(c) The book cost of carrier property retired shall be determined from the carrier's records and if this cannot be done it shall be estimated. When it is impracticable to determine the book cost of each unit, due to the relatively large number or small cost thereof, an appropriate average book cost of the units, with due allowance for any differences in size and character, shall be used as the book cost of the units retired. Oil pipelines must furnish the particulars of such estimates to the Commission, if requested.

13. In Part 352, Instructions for Carrier Property Accounts, instruction 3–14 Accounting units of property is

deleted.

#### Recordkeeping for Units of Property Accounting Regulations for Public Utilities and Licensees, Natural Gas Companies and Oil Pipeline Companies

Docket No. RM97-6-000

Appendix

The commenters on the NOPR are:

- 1. American Electric Power System (AEP),
- 2. American Gas Association (AGA),
- 3. Cinergy Corporation (CINergy),
- 4. Colonial Pipeline Company (Colonial),
- 5. Commonwealth Edison Company (Commonwealth Edison),
- 6. Consumers Energy Company (Consumers Energy),
- 7. Duke Power Company (Duke),
- 8. Edison Electric Institute (EEI),
- 9. Explorer Pipeline Company (Explorer),
- 10. Interstate Natural Gas Association of America (INGAA),
- 1. Lakehead Pipe Line Company, Limited Partnership (Lakehead),
- 12. Marathon Pipe Line Company (Marathon),
- 13. Minnesota Power & Light Company (Minnesota P & L),
- 14. New England Electric System (NEES),
- 15. New York State Electric & Gas Corporation (NSYEG),
- 16. Ohio Edison Company (Ohio Edison),
- 17. Oklahoma Gas & Electric Company (OG&E),
- 18. PECO Energy Company (PECO Energy),
- Joint comments of Public Service Company of Colorado (PSColorado) and Cheyenne Light, Fuel and Power Company (Cheyenne),
- 20. SFPP, L.P. (SFPP), and
- 21. Virginia Electric & Power Company (VEPCO).

[FR Doc. 98–3457 Filed 2–10–98; 8:45 am] BILLING CODE 6717–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

21 CFR Part 177

[Docket No. 97F-0181]

### **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 change the melting point range for propylene homopolymers, intended for use in contact with food, from 160–180 °C to 150–180 °C. This action is in response to a petition filed by Exxon Chemical Co.

**DATES:** The regulation is effective February 11, 1998; written objections and requests for a hearing by March 13, 1998.

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:

Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of May 16, 1997 (62 FR 27060), FDA announced that a food additive petition (FAP 7B4544) had been filed by Exxon Chemical Co., P.O. Box 3272, Houston, TX 77253-3272. The petition proposed to amend the food additive regulations in § 177.1520 Olefin polymers (21 CFR 177.1520), to change the melting point range for propylene polymers, intended for use in contact with food, from 160-180 °C to 150–180 °C. However, the petitioner submitted data and information to support a proposed change in the melting point range from 160–180 °C to 150–180 °C for propylene homopolymers prepared from metallocene catalysts. Therefore, FDA considered a change in the melting point only for propylene homopolymers prepared from metallocene catalysts.

In the **Federal Register** of May 16, 1997 (62 FR 27060), the filing notice for the petition stated that the action resulting from the petition qualified for a categorical exclusion under previous 21 CFR 25.24(9). This was a misprint and should have cited 21 CFR 25.24(a)(9). Upon further review, the agency determined that such a

categorical exclusion, which is based on a technical change in a regulation, is not appropriate for this action because the proposed amendment is not simply a technical change. Consequently, the agency considered the environmental effects of this action.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency determined that the petitioner has adequately demonstrated that propylene homopolymers manufactured by the catalytic polymerization of propylene with a metallocene catalyst, and with a melting point range between 150 °C and 180 °C, conform to the identity and specifications for polypropylene under § 177.1520, in item 1.1(a) in the table in paragraph (c) (previously item 1.1), except for the melting point range specification. Thus, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and (3) the regulations in § 177.1520 should be amended as set forth in this document.

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 previously. 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 March 13, 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.

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

2. Section 177.1520 is amended by redesignating paragraph (a)(1) as paragraph (a)(1)(i), by adding paragraph (a)(1)(ii), and in the table in paragraph (c) by redesignating item 1.1 as item 1.1a, and by revising newly redesignated item 1.1a, and by adding item 1.1b to read as follows:

## § 177.1520 Olefin polymers.

\* \* \* \* \*

(a) \* \* \*

(1) \* \* \*

(ii) Propylene homopolymer consists of basic polymers manufactured by the catalytic polymerization of propylene with a metallocene catalyst.

(c) \* \* \* \* \* \*

Olefin polymers	Density	Melting Point (MP) or softening point (SP) ( <i>Degrees Cen-</i> <i>tigrade</i> )	Maximum extract- able fraction (ex- pressed as percent by weight of the polymer) in <i>N</i> - hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
<ul><li>1.1a Polypropylene described in paragraph (a)(1)(i) of this section</li><li>1.1b Propylene homopolymer described in para-</li></ul>		MP: 160°–180 °C MP: 150°–180 °C	6.4 pct at reflux temperature. 6.4 pct at reflux	9.8 pct at 25 °C 9.8 pct at 25 °C
( )( )()	0.880-0.913	MP: 150°-180 °C		lux

Dated: January 30, 1998.

#### Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition. [FR Doc. 98–3357 Filed 2–10–98; 8:45 am] BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

21 CFR Part 177
[Docket No. 97N-0301]

**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 for Nylon 6/66 resins to change the melting point range from 380–400 °F to 380–425 °F. This action is in response to a petition filed by Ube Industries (America), Inc.

**DATES:** Effective February 11, 1998; written objections and requests for a hearing by March 13, 1998.

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: 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 July 21, 1997 (62 FR 39003), FDA announced that a food additive petition (FAP 7B4548) had been filed by Ube Industries (America), Inc., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 20191. The petition proposed to amend the food additive regulations in § 177.1500 Nylon resins (21 CFR 177.1500), for Nylon 6/66 resins described in the table in paragraph (b), entry 4.2, to change the melting point range from 380-400 °F to 380-425 °F.

The filing notice for the petition (62 FR 39003) stated that the action resulting from the petition qualified for a categorical exclusion under previous 21 CFR 25.24(9). This was a misprint and should have cited 21 CFR 25.24(a)(9). Upon further review, the agency determined that such a categorical exclusion, which is based on a technical change in a regulation, is not appropriate for this proposed action

because the proposed amendment is not simply a technical change. Consequently, the agency considered

the environmental effects of this action. FDA has evaluated data in the petition supporting the chemical identity of the additive and other relevant material. The agency finds that the petitioner has adequately demonstrated that Nylon 6/66 with a melting point that includes the range from 400–425 °F meets the specifications under § 177.1500(b), entry 4.2. Based on this information the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and that therefore, (3) the regulations in § 177.1500 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 March 13, 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.

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

### §177.1500 [Amended]

2. Section 177.1500 *Nylon resins* is amended in the table in paragraph (b) for entry "4.2" under the heading "Melting point (degrees Fahrenheit)" by removing "380–400" and adding in its place "380–425".

Dated: January 30, 1998.

#### Janice F. Oliver,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-3356 Filed 2-10-98; 8:45 am] BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 314

[Docket No. 95N-0010]

# Investigational New Drug Applications and New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations pertaining to new drug applications (NDA's) to clearly define in the NDA format and content regulations the requirement to present effectiveness and safety data for important demographic subgroups, specifically gender, age, and racial subgroups. FDA