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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 175**

[Docket No. 97F-0428]

**Indirect Food Additives: Adhesives and Components of Coatings**

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

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of dimethyl-2,6-naphthalenedicarboxylate and 2,6-naphthalenedicarboxylic acid as polybasic acids intended for use as components of resinous and polymeric coatings that contact food. This action is in response to a petition filed by Amoco Corp.

**DATES:** The regulation is effective (*insert date of publication in the Federal Register*); written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**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 November 20, 1997 (62 FR 62062), FDA announced that a food additive petition (FAP 7B4555) had been filed by Amoco Corp., One Prudential Plaza, 130 East Randolph St., Chicago, IL 60601-6207. The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric*

*coatings* (21 CFR 175.300) to include dimethyl-2,6-naphthalenedicarboxylate and 2,6-naphthalenedicarboxylic acid as polybasic acids intended for use as components of resinous and polymeric coatings that contact food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additives as components of resinous and polymeric coatings that contact food is safe, that the additives will have their intended technical effect, and therefore, that the regulation in § 175.300 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 rule as announced in the notice of filing for FAP 7B4555 (62 FR 62062, November 20, 1997). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before (*insert date 30 days after date of publication in the **Federal Register***), file with the Dockets Management Branch (address above) written objection 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.

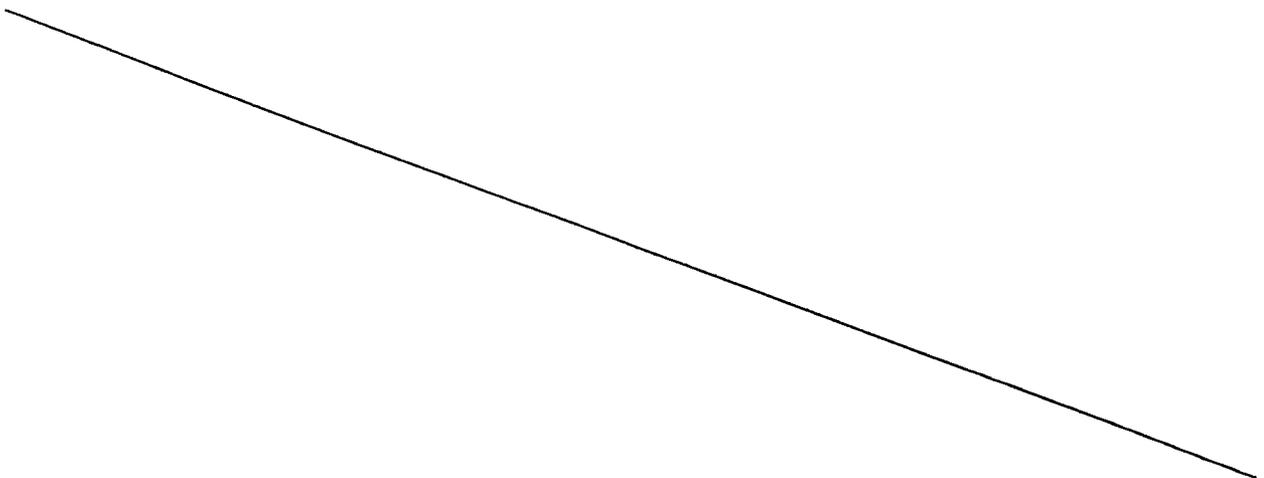
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 175 is amended as follows:

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

2. Section 175.300 is amended in paragraph (b)(3)(vii)(a) by alphabetically adding two entries to read as follows:



§ 175.300 Resinous and polymeric coatings.

\* \* \* \* \*

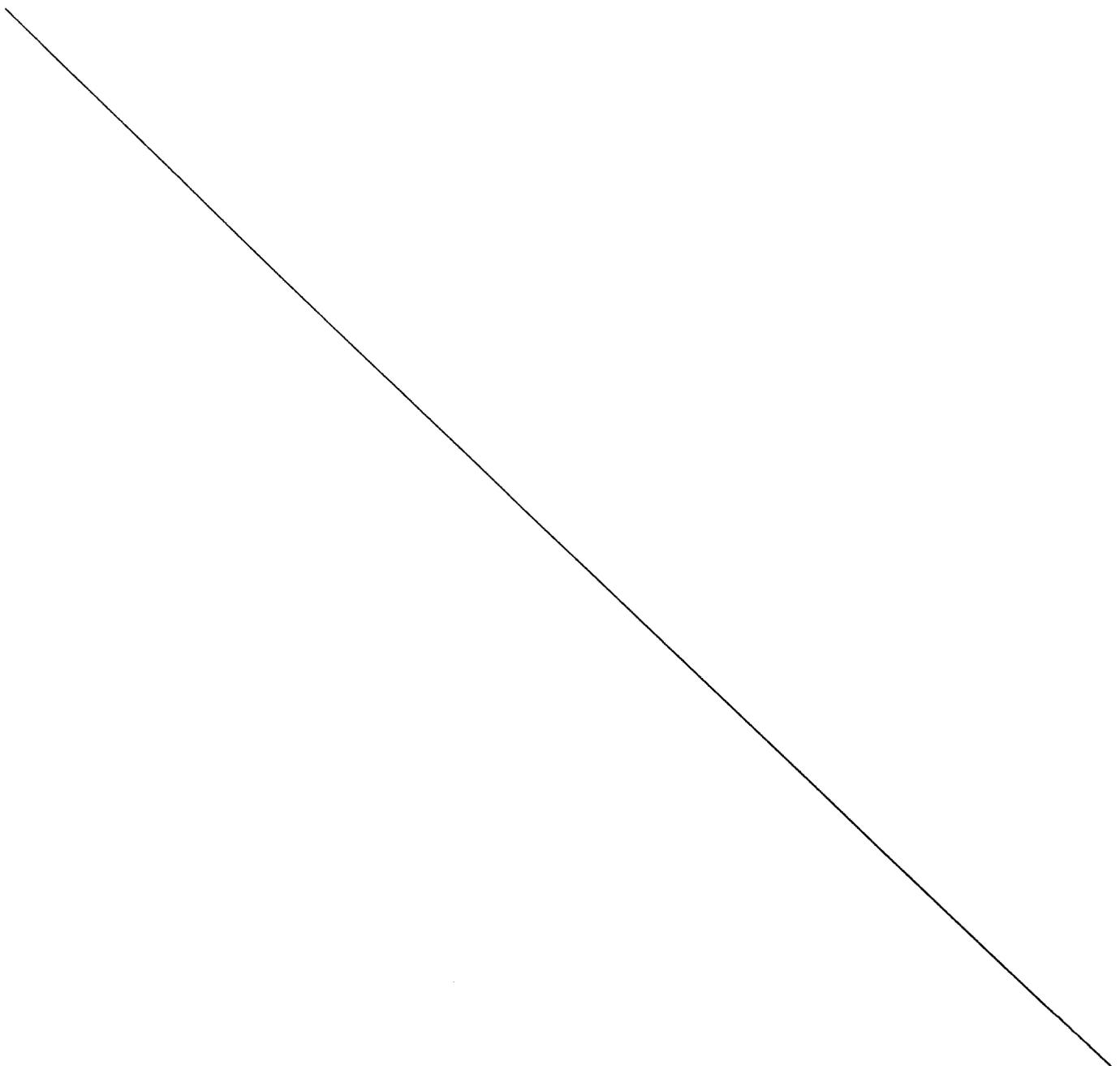
(b) \* \* \*

(3) \* \* \*

(vii) \* \* \*

(a) \* \* \*

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2,6-Naphthalenedicarboxylic.

2,6-Naphthalenedicarboxylic, dimethyl ester.

\* \* \* \* \*

Dated: 10/16/98

October 16, 1998

L. Robert Lake

L. Robert Lake  
Director  
Office of Policy, Planning and Strategic Initiatives  
Center for Food Safety and Applied Nutrition

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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*Olga Borders*