which has been reworded to read NDB. The FAA has determined that this change is editorial in nature and will not increase the scope of this rule. Except for the non-substantive change just discussed, the rule is adopted as written.

The area will be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 of FAA Order 7400.9F, *Airspace Designations and Reporting Points,* dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1 (63 FR 50139; September 21, 1998). The Class E airspace designations listed in this document will be revised and published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 revises the Class E airspace at Anaktuvuk Pass, AK, due to the establishment of a GPS instrument approach at Anaktuvuk Pass, AK. The Anaktuvuk Pass Airport status is upgraded from VFR to IFR. The intended effect of this action is to provide adequate controlled airspace for IFR operations at Anaktuvuk Pass, AK.

The FAA has determined that these proposed regulations only involve an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore —(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71— DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9F, *Airspace Designations and Reporting Points,* dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth

* * * * *

AAL AK E5 Anaktuvuk Pass, AK [New]

Anaktuvuk Pass Airport, AK
(Lat. 52°13′15″ N., long. 174°12′39″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Anaktuvuk Pass Airport and within 5 miles either side of the Anaktuvuk Pass NDB 240° bearing extending from the NDB to 7 miles southwest of the airport.

* * * * *

Issued in Anchorage, AK, on October 28, 1998.

Trent S. Cummings,

Acting Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 98–29627 Filed 11–4–98; 8:45 am]

BILLING CODE 4910–13–P

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.

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 November 5, 1998; written objections and requests for a hearing by December 7, 1998.

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 December 7, 1998, 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*) * * *

* * * * *

2,6-Naphthalenedicarboxylic.

2,6-Naphthalenedicarboxylic, dimethyl ester.

* * * * *

Dated: October 16, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives.

[FR Doc. 98–29615 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 98F–0054]

Indirect Food Additives: Paper and Paperboard Components

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 octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea, and the acetate salts thereof, which may be emulsified with ethoxylated tallow alkyl amines, for use in the manufacture of paper and paperboard intended for use in contact with dry food. This action is in response to a petition filed by Sequa Chemicals, Inc.

DATES: The regulation is effective November 5, 1998; submit written objections and requests for a hearing by December 7, 1998.

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: 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 February 9, 1998 (63 FR 6571), FDA announced that a food additive petition (FAP 8B4576) had been filed by Sequa Chemicals, Inc., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). The petition proposed to amend the food additive regulations in § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) to provide for the safe use of octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea, and the acetate salts thereof, which may be emulsified with ethoxylated tallow alkyl amines, for increasing opacity and thickness, employed prior to the sheet forming operation in the manufacture of paper and paperboard intended for use in contact with dry food.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of ethylene oxide, a carcinogenic impurity resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the so-called ''general safety clause'' of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additive anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, octadecanoic acid, reaction products with 2-[(2-aminoethyl)amino]ethanol and urea, and the acetate salts thereof, which may be emulsified with ethoxylated tallow alkyl amines, will result in exposure to no greater than 50 parts per billion (ppb)