significant adverse impact on the human environment.[4] The Commission has categorically excluded certain actions from these requirements as not having a significant effect on the human environment.[5] The actions proposed to be taken here fall within categorical exclusions in the Commission's regulations for rules that are clarifying, corrective, or procedural, for information gathering, analysis, and dissemination, and for sales, exchange, and transportation of natural gas that requires no construction of facilities.[6] Therefore, an environmental assessment is unnecessary and has not been prepared for this final rule.

V. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (RFA) requires agencies to prepare certain statements, descriptions and analyses of proposed rules that will have an impact on a substantial number of small entities.[7] The Commission is not required to make such analyses if a rule would not have such an effect.[8]

In the Commission's view, this rule would not have a significant economic impact on small entities. The companies that are regulated by the Commission, who would have to designate a corporate official to receive service, generally do not meet the RFA's definition of a small entity.[9] Further, it would be easier for any small entity to serve a pleading on a regulate company if that company had a specific official designated to receive service. Therefore, the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities.

VI. Effective Date

The regulations are effective December 17, 1999. The Small Business Regulatory Enforcement Fairness Act of 1996 requires agencies to report to Congress certain final rules prior to their effective dates.[10] Since this final rule concerns agency practice and procedure, a determination as to whether it is a major or non-major rule is not necessary and Congressional notification is not required.

[4] Order No. 486, Regulations Implementing the National Environmental Policy Act, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. Preambles 1986–1990 ¶ 30,783 (1987).

[5] 18 CFR 380.4.

[6] See 18 CFR 380.4(a)(2)(ii), 380.4(a)(5), 380.4(a)(27).

[7] 5 U.S.C. 601–612.

[8] 5 U.S.C. 605(b).

[9] 5 U.S.C. 601(3).

[10] 5 U.S.C. 801.

List of Subjects in 18 CFR Part 385

Administrative practice and procedure, Electric power, Penalties, Pipelines, Reporting and recordkeeping requirements.

By the Commission.

David P. Boergers,

Secretary.

In consideration of the foregoing, the Commission amends Part 385, Chapter I, Title 18, *Code of Federal Regulations*, as follows.

PART 385—RULES OF PRACTICE AND PROCEDURE

1. The authority citation for Part 385 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717z, 3301–3432; 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; 49 U.S.C. 60502; 49 App. U.S.C. 1–85.

2. In § 385.2010, new paragraph (i) is added to read as follows:

§ 385.2010 Service (Rule 2010)

* * * * *

(i) *Designation of Corporate Officials to Receive Service.* (1) Any entity subject to regulation by the Commission must designate at least one, but not more than two, corporate officials or other persons to receive service of complaints, petitions for declaratory order, show cause orders, data requests, investigatory letters or other documents where a person to receive service has not otherwise been designated under Commission regulations. Each entity must file with the Secretary of the Commission:

(i) The name of the corporate official or person that is to receive service;

(ii) The title of the corporate official or person, if applicable;

(iii) The address of the corporate official or person, including, where applicable, department, room number, or mail routing code;

(iv) The telephone number of the corporate official or person;

(v) The facsimile number of the corporate official or person, if applicable; and

(vi) The electronic mail address of the corporate official or person, if applicable.

(2) Each regulated entity has a continuing obligation to file with the Secretary of the Commission updated information concerning the corporate official or person designated to receive service.

(3) A list of corporate officials and persons designated to receive service pursuant to this paragraph will be maintained by the Secretary of the Commission and will be made available to the public in hard copy upon request and through the Commission's web site at http://www.ferc.fed.us.

(4) Any person who wishes to serve a complaint or petition for declaratory order on any entity regulated by the Commission must serve the corporate official or person designated pursuant to this paragraph (i).

(5) The Commission will serve show cause orders, data requests, investigatory letters or other documents on the corporate official or person designated under this paragraph (i).

[FR Doc. 99–29979 Filed 11–16–99; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 92C–0348]

Listing of Color Additives for Coloring Bone Cement; FD&C Blue No. 2–Aluminum Lake on Alumina; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of October 5, 1999 (64 FR 48288), for the final rule that appeared in the **Federal Register** of September 3, 1999, and that amended the color additive regulations to provide for the safe use of FD&C Blue No. 2–Aluminum Lake on alumina to color bone cement. The agency also transferred the listing for the use of FD&C Blue No. 2 in sutures to reflect that sutures in which this color additive is used are devices, not drugs.

DATES: Effective date confirmed: October 5, 1999.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 3, 1999 (64 FR 48288), FDA amended the color additive regulations to provide for the safe use of FD&C Blue No. 2–Aluminum Lake on alumina to color bone cement. To reflect that sutures in which this color additive is used are devices, not drugs, the agency also transferred the listing for the use of FD&C Blue No. 2

in sutures from § 74.1102 *FD&C Blue No. 2* (21 CFR 74.1102) under subpart B—Drugs to new § 74.3102 *FD&C Blue No. 2* (21 CFR 74.3102) under subpart D—Medical Devices and made nonsubstantive amendments to § 74.1102.

FDA gave interested persons until October 4, 1999, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the **Federal Register** of September 3, 1999, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the September 3, 1999, final rule. Accordingly, the amendments issued thereby became effective October 5, 1999.

Dated: November 9, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–29917 Filed 11–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 98F–0492]

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 expanded safe use of *N*,*N*-bis (2-hydroxyethyl) alkyl (C_{13}-C_{15}) amine as an antistatic agent in polypropylene homo- and copolymers intended for contact with food. This action is in response to a petition filed by ICI PLC.

DATES: This regulation is effective November 17, 1999; written objections and requests for a hearing by December 17, 1999.

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: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), 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 July 7, 1998 (63 FR 36699), FDA announced that a food additive petition (FAP 8B4602) had been filed by ICI PLC, c/o ICI Surfactants, P.O. Box 8340, Wilmington, DE 19803–8340. 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 expanded safe use of *N*,*N*-bis (2-hydroxyethyl) alkyl (C_{13}-C_{15}) amine as an antistatic agent in polypropylene homo- and copolymers intended for contact with food.

In its evaluation of the safety of this food additive, FDA has reviewed the safety of the additive itself, the starting materials used, 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 unreacted 1,4-dioxane and ethylene oxide, which are carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of impurities, such as 1,4-dioxane and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the general safety standard 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 additives 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, *N*,*N*-bis (2-hydroxyethyl) alkyl (C_{13}-C_{15}) amine, will result in exposure to no greater than 23 parts per billion (ppb) of the additive in the daily diet (3 kilograms (kg)) or an estimated daily intake of 69 micrograms per person per day (μg/p/d) (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that the estimated small dietary exposure resulting from the petitioned use of this additive is safe.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by 1,4-dioxane and ethylene oxide, the carcinogenic chemicals that may be present as impurities in the additive. This risk evaluation of 1,4-dioxane and ethylene oxide has two aspects: (1) Assessment of exposure to the impurities from the petitioned use of the additive, and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

A. 1,4–Dioxane

FDA has estimated the exposure to 1,4-dioxane from the petitioned use of the additive as an antistatic agent in polypropylene homo- and copolymers intended for contact with food to be no more than 0.09 ppb in the daily diet (3 kg), or 0.28 μg/p/d (Ref. 1). The agency used data from a carcinogenesis bioassay on 1,4-dioxane, conducted by the National Cancer Institute (Ref. 3), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The results of the bioassay on 1,4-dioxane