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.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. DiNovi, M., Memorandum to L. Tarantino, May 23, 1995.

2. Bleiberg, M., Memorandum to B. Anderson et al., November 4, 1993.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

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 of the Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section 172.859 is amended by revising paragraphs (c)(1) and (c)(2) to read as follows:

§ 172.859 Sucrose fatty acid esters.

* * * * *

(c) * * *

(1) As emulsifiers as defined in § 170.3(o)(8) of this chapter, or as stabilizers as defined in § 170.3(o)(28) of this chapter, in baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter, in chewing gum as defined in § 170.3(n)(6) of this chapter, in coffee and tea beverages with added dairy ingredients and/or dairy product analogues, in confections and frostings as defined in § 170.3(n)(9) of this chapter, in dairy product analogues as defined in § 170.3(n)(10) of this chapter, in frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter, and in whipped milk products.

(2) As texturizers as defined in § 170.3(o)(32) of this chapter in biscuit mixes, in chewing gum as defined in § 170.3(n)(6) of this chapter, in confections and frostings as defined in § 170.3(n)(9) of this chapter, and in surimi-based fabricated seafood products.

* * * * *

Dated: August 8, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–21378 Filed 8–28–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 176

[Docket No. 93F–0335]

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 ammonium zirconium lactate-citrate complexes for use as insolubilizers for clay coatings with protein binders in coatings for paper and paperboard intended for use in contact with food. This action is in response to a food additive petition filed by Sequa Chemicals, Inc.

DATES: Effective August 29, 1995; written objections and requests for a hearing by September 28, 1995.

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

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3084.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 15, 1993 (58 FR 53518), FDA announced that a food additive petition (FAP 3B4386) had been filed by Sequa Chemicals, Inc., One Sequa Dr., Chester, SC 29706–0070. The petition proposed that the food additive regulations be amended to provide for the safe use of ammonium zirconium lactate-citrate complexes for use as insolubilizers for binders used in clay coatings for paper and paperboard intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based upon its review, the agency concludes that the use of ammonium zirconium lactate-citrate complexes should be limited to use as insolubilizers only for clay coatings with protein binders in coatings for paper and paperboard. The agency also concludes that, as so limited, the proposed food additive use is safe, and that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) 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 21 CFR 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 September 28, 1995 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 176

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 of the Center for Food Safety and Applied Nutrition, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: Secs. 201, 402, 406, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348 379e).

2. Section 176.170 is amended in the table in paragraph (a)(5) by alphabetically adding a new entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

List of substances	Limitations
* * * * *	
Ammonium zirconium citrate (CAS Reg. No. 149564–62–5), ammonium zirconium lactate-citrate (CAS Reg. No. 149564–64–7), ammonium zirconium lactate (CAS Reg. No. 149564–63–6).	For use as insolubilizers only for clay coatings with protein binders in coatings for paper and paperboard, at a level not to exceed 1.4 percent by weight of coating solids.
* * * * *	

* * * * *

Dated: August 17, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–21380 Filed 8–28–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 90F–0364]

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-ethylhexyl)-*a*r-methyl-1*H*-benzotriazole-1-methanamine as a copper deactivator for lubricants with incidental food contact. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective August 29, 1995; written objections and requests for a hearing by September 28, 1995.

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

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), 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 November 21, 1990 (55 FR 48693), FDA announced that a food additive petition (FAP 1B4233) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188, proposing that § 178.3570 *Lubricants with incidental food contact* (21 CFR 178.3570) be amended to provide for the safe use of *N*,*N*-bis(2-ethylhexyl)-*a*r-methyl-1*H*-benzotriazole-1-methanamine as a copper deactivator for lubricants with incidental food contact complying with 21 CFR 178.3570.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe and that the regulations in § 178.3570(a)(3) should be amended as set forth below.

FDA's review of the subject petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years formaldehyde has been known to be a carcinogen by the inhalation route, but it concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til et al. (1989), conducted in The Netherlands (Ref. 2). The Committee reviewed both studies and concluded, ''* * * that data concerning the Soffritti study reported were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical details in the study, questionable histopathologic conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

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 21 CFR 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 September 28, 1995, file with the Dockets Management