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 objection 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.

VI. 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. Memorandum from the Chemistry Review Team, FDA, to the file concerning ''FAP 6B4523 (MATS #887, M2.0 & 2.1): Dow Chemical Co., dated September 18, 1996. Epichlorohydrin-dipropylene Glycol and Epichlorohydrin-polypropylene Glycol as Reactants in the Preparation of Epoxy Resins Used in Adhesives,'' dated October 29, 1996.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger, J. K. Marquis, and S. Karger, New York, NY, pp. 24–33, 1985.

3. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2–Propylene Oxide Upon Intragastric Administration to Rats,'' *British Journal of Cancer*, 46: pp. 924–933, 1982.

4. Memorandum from the Indirect Additives Branch, FDA, to the Executive Secretary, Quantitative Risk Assessment Committee, FDA, concerning ''Estimation of Upper-bound Lifetime Risk from Propylene Oxide and Epichlorohydrin Epoxy Resins Employed as Reactants in the Preparation of Epoxy Resins Used in Adhesives: Subject of Food Additive Petition No. 6B4523 (Dow Chemical Company),'' dated November 12, 1996.

5. Konishi, Y. et al., ''Forestomach Tumors Induced by Orally Administered Epichlorohydrin in Male Wistar Rats,'' *Gann*, 71: pp. 922–923, 1980.

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

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding new entries under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * *	* * * *
α-(oxiranylmethyl)-ω-(oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], (alternative name: epichlorohydrin-polypropylene glycol) (CAS Reg. No. 26142–30–3).	For use as a reactant in the preparation of epoxy-based resins.
2,2'-[oxybis[(methyl-2,1-ethanediyl)-oxymethylene]]bisoxirane, (alternative name: epichlorohydrin-dipropylene glycol) (CAS Reg. No. 41638–13–5).	For use as a reactant in the preparation of epoxy-based resins.
* * *	* * * *

Dated: July 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–19567 Filed 7-24-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 96F–0291]

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 12-hydroxystearic acid-polyethylene glycol (minimum MW 200) block copolymer as a surfactant in the manufacture of paper and paperboard intended for use in contact with food. This action is in response to a petition filed by ICI Americas, Inc.

DATES: Effective July 25, 1997; written objections and requests for a hearing by August 25, 1997.

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 August 26, 1996 (61 FR 43772), FDA announced that a food additive petition (FAP 6B4519) had been filed by ICI Americas, Inc., 3411 Silverside Rd., Wilmington, DE 19850. The petition proposed to amend the food additive regulations in § 176.170 Components of paper and paperboard in contact with aqueous and fatty foods (21 CFR 176.170) to provide for the safe use of 12-hydroxystearic acid-polyethylene glycol (minimum MW 200) block copolymer as a surfactant in the manufacture of paper and paperboard intended for use in contact with 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 unreacted 1,4-dioxane and ethylene oxide, carcinogenic impurities resulting from

the manufacture of the additive. Residual amounts of reactants and manufacturing aids, 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, 12-hydroxystearic acid-polyethylene glycol (minimum MW 200) block copolymer as a surfactant in the manufacture of paper and paperboard will result in exposure to the additive of no greater than 15 parts per billion in the daily diet (3 kilogram (kg)) or an estimated daily intake of 45 microgram per person per day (ug/p/d) (Ref. 1).

FDA does not ordinarily consider chronic toxicological testing 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 the 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 the 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 in the manufacture of paper and paperboard to be 1.5 parts per quadrillion (pp quad) of the daily diet (3 kg) or 4.5 picogram (pg)/person/day (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 lifetime human risk from exposure to this chemical stemming from the petitioned use of the additive. The results of the bioassay on 1,4-dioxane demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused a significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

Based on the agency's estimate that exposure to 1,4-dioxane will not exceed 4.5 pg/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the use of the subject additives is 1.6×10^{-13} (or 1.6 in 10 trillion) (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 1,4-dioxane is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to 1,4-dioxane would result from the petitioned use of the additive.

B. Ethylene oxide

FDA has estimated the exposure to ethylene oxide from the petitioned use of the additive in the manufacture of paper and paperboard to be 1.5 pp quad of the daily diet (3 kg) or 4.5 pg/person/day (Ref. 1). The agency used data from a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, Germany (Ref. 5), 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 ethylene oxide demonstrated that ethylene oxide was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas of the forestomach and carcinomas in situ of the glandular stomach.

Based on the agency's estimate that the exposure to ethylene oxide will not exceed 4.5 pg/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additives is 8.4×10^{-12} (or 8.4 in 1 trillion)) (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to ethylene oxide is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to ethylene oxide would result from the petitioned use of the additive.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of 1,4-dioxane and ethylene oxide as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which 1,4-dioxane and ethylene oxide may be expected to remain as impurities following production of the additives, the agency would not expect the impurities to become components of food at other than an extremely small level; and (2) the upper-bound limits of lifetime risk from exposure to 1,4-dioxane and ethylene oxide, even under worst-case assumptions, is very low, 1.6 in 10 trillion and 8.4 in 1 trillion, respectively.

III. Conclusion

FDA has evaluated data in the petition and other relevant material. 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 § 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 § 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.

IV. Environmental Impact

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. No comments were received during the 30 day comment period specified in the filing notice for comments on the environmental assessment submitted with the petition.

V. Objections

Any person who will be adversely affected by this regulation may at anytime on or before August 25, 1997 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 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 objection 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.

VI. 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. Memorandum from the Chemistry Review Team, FDA, to the file concerning ''FAP 6B4519 (MATS #882, M2.0 & 2.1): ICI Americas Inc., dated July 23, 1996. Use of 12-hydroxystearic acid-propylene glycol (MW 200) Block Copolymer as an Adjuvant in the Manufacture of Paper and Paperboard,'' dated August 20, 1996.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger, J. K. Marquis, and S. Karger, New York, NY, pp. 24–33, 1985.

3. ''Bioassay of 1,4-Dioxane for Possible Carcinogenicity,'' National Cancer Institute, NCI-CG-TR-80, 1978.

4. Memorandum from the Indirect Additives Branch, FDA, to the Executive Secretary, Quantitative Risk Assessment Committee, FDA, concerning ''Estimation of Upper-bound Lifetime Risk from Ethylene Oxide and 1,4-dioxane in 12-hydroxystearic acid-polyethylene glycol (MW 200) Block Copolymer as an Adjuvant in the Manufacture of Paper and Paperboard: Subject of Food Additive Petition No. 6B4519 (ICI Americas Inc.),'' dated March 3, 1996.

5. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2-propylene Oxide Upon Intrgastric Administration to Rats,'' *British Journal of Cancer*, 46: pp. 924–933, 1982.

List of Subjects in 21 CFR Part 175

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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 revising the entry for ''12-Hydroxystearic acid-polyethylene glycol block copolymers (CAS Reg. No. 70142–34–6)'' to read as follows:

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

* * * * *

(a) * * *

(5) * * *

List of Substances	Limitations
* * *	* * * *
12-Hydroxystearic acid-polyethylene glycol block copolymers (CAS Reg. No. 70142–34–6) produced by the reaction of polyethylene glycol (minimum molecular weight 200) with 12-hydroxystearic acid.	For use only as a surfactant for dispersions of polyacrylamide retention and drainage aids employed prior to the sheet forming operation in the manufacture of paper and paperboard.
* * *	* * * *

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Dated: July 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–19568 Filed 7-24-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8–R]

RIN 0720–AA36

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Extension of the Active Duty Dependents Dental Plan to Overseas Areas

AGENCY: Office of the Secretary, DoD.

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule implements recently enacted statutory authority for the extension of the Active Duty Dependents Dental Plan to overseas areas. It provides for adjustments in the program in overseas areas. This rule details the implementation and operation of the program which will ensure access to dental care for family members accompanying their active sponsors while overseas.

DATES: This interim final rule is effective August 25, 1997. Comments may be submitted on or before September 23, 1997.

ADDRESSES: Forward comments to TRICARE Support Office (TSO)/Office of the Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), Office of Program Development; Aurora, Colorado 80045–6900.

FOR FURTHER INFORMATION CONTACT: Mr. Gunther J. Zimmerman, Office of the Assistant Secretary of Defense (Health Affairs), (703) 695–3331.

SUPPLEMENTARY INFORMATION:

1. Overview of the Interim Final Rule

Military force reductions in Europe, the Middle East, and the Pacific have resulted in diminished medical services for many areas, particularly those where the active duty end strengths have fallen below levels which would support a military medical facility. Service members and their families, particularly those in remote areas, have experienced significant access problems in obtaining dental services at military facilities. This rule is based on section 703 of the National Defense Authorization Act for Fiscal Year 1995, Public Law 103–337, which amended 10 U.S.C. 1076a. This law allows the Department to extend the Dependent's Dental Plan to overseas areas. Family members enrolled in the Dependent's Dental Plan will be allowed to receive dental care from host nation providers and have the dental claims processed by a dental contractor. Host nation providers who meet accepted dental practice standards will be identified by the local military dental treatment facility commander.

Enrolled family members overseas will be eligible to obtain the same basic dental benefits offered to enrollees in the Active Duty Dependents' Dental Plan (also referred to as the TRICARE Active Duty Family Member Dental Plan) in the Continental United States. The Continental United States is defined as the forty-eight contiguous states, as well as Alaska, Hawaii, Guam, Puerto Rico, the District of Columbia, the U.S. Virgin Islands and Canada. Overseas is defined as those countries not previously mentioned.

This interim final rule will allow dental claims to be paid on a ''billed charge'' basis. In order to participate, beneficiaries must be enrolled in the Family Member Dental Plan (FMDP). In order to have care from host nation dentists reimbursed under the FMDP, beneficiaries will be requested to be referred by a military dental treatment facility (DTF). This referral will be contingent upon the lack of availability of the applicable dental services in the DTF. Beneficiaries will receive evidence of preauthorization. Family members residing with their active duty sponsor in remote locations where there are no DTFs will not be required to obtain a Nonavailability Statement (NAS) to receive care. Countries will be considered remote locations for the purpose of NAS's when the Department does not have a significant presence and no fixed dental treatment facilities. Family members in these countries may obtain care from any host nation provider meeting accepted U.S. standards. The dental claims processor, upon receiving a claim without an attached authorization, will review the claim to determine if it is from a family member in a remote location. Following this verification, the claim will be processed under the ODP benefit plan.

Basic dental care encompasses diagnostic and preventive (exams, x-rays, cleanings, etc), sealants (for children under age 14), restorative (fillings, crowns, etc), endodontics (root canals, etc.), periodontics (gum surgery, etc.), oral surgery (extractions, etc.), and prosthodontics (bridges, dentures, etc.). An annual cap (contract year—August 1 to July 31) of $1,000 is applicable to basic dental care. Orthodontics is available, subject to the lifetime maximum of $1,200 per member. In the event either of these maximum caps (annual dental or lifetime orthodontics) is insufficient to enable beneficiaries to obtain the required dental care, the responsible dental facility has the authority to issue a waiver on behalf of the beneficiary. This waiver review will be accomplished on a prospective basis, for dental care required due to extraordinary circumstances governing the cost of dental services in a particular geographic area.

All requests from DTFs to their Service Dental chiefs for waiver from the maximum caps will be handled in accordance with procedures established by the Service Dental Chiefs. Waiver requests should include the beneficiary's latest Explanation of Benefit (EOB) to indicate the beneficiary's current value of dental care applicable to the cap level; information on the proposed treatment; and information on the costs of dental care in the host nation compared to overall dental costs in the United States.

II. Rulemaking Procedures

Executive Order 12866 requires certain regulatory assessments for any ''significant regulatory action,'' defined as one which would result in an annual effect on the economy of $100 million or more, or have other substantial impacts.

The Regulatory Flexibility Act (FRA) requires that each Federal Agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities.

This is not a significant regulatory action under the provisions of Executive Order 12866, and it would not have a significant impact on a substantial number of small entities, however, this rule has been reviewed by OMB.

The interim final rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 55).

The Department is publishing this rule as an interim final rule in order to implement the program in a timely manner. Regulations involving military affairs are exempt from the notice and comment rulemaking procedures of the Administrative Procedures Act. Because this rule deals exclusively with a