Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

AD 99–23–03 Bell Helicopter Textron Canada: Amendment 39–11399. Docket No. 98–SW–50–AD.

Applicability: Model 430 helicopters, serial numbers 49001 through 49036, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of torque of the vertical fin attachment bolts (bolts), which could lead to fracture of the bolts, separation of the vertical fin from the helicopter, and subsequent loss of control of the helicopter accomplish the following:

(a) Within 25 hours time-in-service (TIS), verify the torque on the bolts in accordance with Part I of the Accomplishment Instructions in Bell Helicopter Textron Alert Service Bulletin No. 430–98–5, dated June 12, 1998 (ASB).

(b) On or before the next scheduled 150-hour TIS inspection, modify the tailboom and vertical fin and replace the attachment hardware in accordance with Part II of the Accomplishment Instructions in the ASB.

(c) After accomplishing the modification required by paragraph (b) and after at least 5 hours TIS but within 10 hours TIS, verify the torque on the bolts in accordance with Part III of the Accomplishment Instructions in the ASB.

(d) Thereafter, at intervals not to exceed 150 hours TIS, verify the torque of the vertical fin attachment bolts in accordance with the 150 flight hour scheduled inspections, Part III, of the Accomplishment Instructions in the ASB.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(g) The inspections shall be done in accordance with Bell Helicopter Textron Canada Alert Service Bulletin No. 430–98–5, dated June 12, 1998.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bell Helicopter Textron Canada, 12,800 Rue de l'Avenir, Mirabel, Quebec JON1LO, telephone (800) 463–3036, fax (514) 433–0272. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on November 19, 1999.

Note 3: The subject of this AD is addressed in Transport Canada (Canada) AD CF–98–23, dated August 7, 1998.

Issued in Fort Worth, Texas, on October 26, 1999.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 99–28652 Filed 11–3–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 91F–0431]

Indirect Food Additives: Resinous and Polymeric 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 2,2'-[(1-methylethylidene)bis[4,1-phenyleneoxy[1-(butoxymethyl)-2,1-ethanediyl]oxymethylene]]bisoxirane as a component of epoxy coatings intended for use in contact with bulk dry foods. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: This regulation is effective November 4, 1999; written objections and requests for a hearing by December 6, 1999.

ADDRESS: 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: Vivian Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3094.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of December 5, 1991 (56 FR 63737), FDA announced that a food additive petition (FAP 1B4278) had been filed by Ciba–Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188. The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of 2,2'-[(1-methylethylidene)bis[4,1-phenyleneoxy[1-(butoxymethyl)-2,1-ethanediyl]oxymethylene]]bisoxirane as a component of resinous and polymeric coatings intended for use in contact with dry bulk foods.

In FDA's evaluation of the safety of this additive, the agency 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 epichlorohydrin, a carcinogenic impurity resulting from the manufacture of the additive. Residual amounts of impurities are commonly found as constituents of chemical products, including food additives.

II. 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 the 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)).

III. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, 2,2'-[(1-methylethylidene)bis[4,1-phenyleneoxy[1-(butoxymethyl)-2,1-ethanediyl]oxymethylene]]bisoxirane, will result in exposure no greater than 4.4 parts per (pp) trillion of the additive in the daily diet (3 kilograms (kg)) or an estimated daily intake (EDI) of 13 nanograms per person per day (ng/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 epichlorohydrin, a carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of epichlorohydrin has two aspects: (1) Assessment of the exposure to the impurity from the petitioned use of the additive and (2) extrapolation of the risk observed in the animal bioassay to the conditions of exposure to humans.

A. Epichlorohydrin

FDA has estimated the exposure to epichlorohydrin from the petitioned use of the additive as a component of epoxy coatings to be no more than 0.013 pp trillion of the daily diet (3 kg), or 39 picograms/person/day (pg/p/d) (Ref.3). The agency used data from a carcinogenesis bioassay conducted on rats fed epichlorohydrin via their drinking water (Ref. 4), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The authors reported that the test material caused significantly increased incidence of stomach papillomas and carcinomas in rats.

Based on the agency's estimate that exposure to epichlorohydrin will not exceed 39 pg/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 1.8 X 10–12, or 1.8 in one trillion (Ref. 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to epichlorohydrin 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 epichlorohydrin would result from the petitioned use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of epichlorohydrin present as an impurity in the food additive. The agency finds that specifications are not necessary for the following reasons: (1) Because the low levels at which epichlorohydrin may be expected to remain as an impurity following production of the additive, the agency would not expect this impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime human risk from exposure to epichlorohydrin is very low, 1.8 in a trillion.

IV. 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 § 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.

V. Environmental Impact

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment (EA) nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

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.

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before December 6, 1999, 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 (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. 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 Division of Product Manufacture and Use, Chemistry Review Team (HFS–246), to the Division of Petition Control (HFS–215), entitled ''FAP 1B4278 (MATS #583, M2.2.1): Ciba–Geigy Corp., Request from DHEE dated 12–16–97 for a revised exposure estimate to Araldite XU GY 376, an epoxy resin for use as a repeat-use coating component that will contact bulk grains and dry foods,'' dated February 27, 1998.

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

3. Memorandum from the Chemistry Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216), entitled ''FAP–1B4278 (MATS #583) Ciba-Geigy Corp., Submission dated 10–23–92. Araldite XU GY 376 as a component of food-contact coatings,'' dated May 12, 1993.

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

5. Memorandum from the Indirect Additives Branch (HFS–216) to the Executive Secretary, Quantitative Risk Assessment Committee (QRAC) (HFS–308) entitled ''Estimation of the upper bound lifetime risk from epichlorohydrin in 2,2'-[(1-methylethylidene)bis[4,1-phenyleneoxy[1-(butoxymethyl)-2,1-ethanediyl]oxymethylene]] bisoxirane, the subject of FAP 1B4278 (Ciba-Geigy Corp.),'' dated November 22, 1993.

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. 21 U.S.C. 321, 342, 348, 379e.

2. Section 175.300 is amended in paragraph (b)(3)(viii)(*a*) by alphabetically adding an entry to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(b) * * *

(3) * * *

(viii) * * *

(*a*) * * *

* * * * *

2,2'-[(1-methylethylidene)bis[4,1-phenyleneoxy[1-(butoxymethyl)-2,1-ethanediyl]oxymethylene]]bisoxirane, CAS Reg. No. 71033–08–4, for use only in coatings intended for contact with bulk dry foods at temperatures below 100 ½F.

* * * * *

Dated: October 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28850 Filed 11–3–99; 8:45 am]

BILLING CODE 4160–01–F

POSTAL SERVICE

39 CFR Part 20

Priority Mail Global Guaranteed

AGENCY: Postal Service.

ACTION: Amendment to interim rule.

SUMMARY: On April 19, 1999, the Postal Service announced in the **Federal Register** (62 FR 19039–19042) the introduction of Priority Mail Global Guaranteed on an interim basis and requested comment from the public. Comments were received until May 19, 1999. The Postal Service is amending the interim rule to increase the number of acceptance locations and destination countries and territories. All other conditions of service, including rates, remain the same. Additionally, the Postal Service is responding to the public comments.

EFFECTIVE DATE: November 1, 1999. Comments on the amendment to the interim rule must be received on or before December 6, 1999.

ADDRESSES: Written comments should be mailed or delivered to the Manager, International Finance, International Business, U.S. Postal Service, 475 L'Enfant Plaza SW, Room 370–IBU, Washington, DC 20260–6500. Copies of all written comments will be available for public inspection between 9 a.m. and 4 p.m., Monday through Friday, in International Business, 10th Floor, 901 D Street SW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Walter J. Grandjean, (202) 314–7256.

SUPPLEMENTARY INFORMATION: On April 19, 1999, the Postal Service announced in the **Federal Register** (62 FR 19039–19042) the introduction of Priority Mail Global Guaranteed on an interim basis and requested comment from the public.

The U.S. Postal Service, through an alliance with DHL Worldwide Express Inc., is offering an enhanced expedited service, Priority Mail Global Guaranteed, from selected locations in the United States to selected countries. This service offers day-certain delivery with postage refund guarantee and document reconstruction coverage of $100 for allowable contents. Comments were requested by May 19, 1999.

By that date the Postal Service received comments from one company, United Parcel Service (UPS), concerning the interim rule. UPS challenged the service in two areas. First, UPS argued that the Postal Service-DHL contract pursuant to which the service is provided appears to be an unauthorized transaction that is contrary to law. Second, UPS asserts that the rates for Priority Mail Global Guaranteed may be below cost, in violation of the Postal Reorganization Act.

UPS states that the arrangement with DHL provides for the air transportation of mail. UPS asserts that this is a contract for air transportation services and that such a contract must comply with 39 U.S.C. 5402, which requires that contracts be filed with the Secretary of Transportation, that contracts be for at least 750 pounds of mail per flight, and that mail transported under contract consist of not more than 5 percent letter mail by weight. UPS's premise for these comments, that there is a contract between the Postal Service and DHL for the transportation of PMGG, is not correct. No such contract has been made. PMGG items are tendered to DHL as an air carrier authorized to transport mail by its certificate of public convenience and necessity in the same manner as mail is tendered to other certificated air carriers. The rates of compensation for the international air transportation service performed by DHL are as prescribed by the Secretary of Transportation under section 41901(b). As there is no contract for air carriage, there is no basis for UPS's comments in this respect.

UPS asserts that the rates for Priority Mail Global Guaranteed may be below