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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 96F-0248]

**Secondary Direct Food Additives Permitted in Food for Human Consumption;
Sulphopropyl Cellulose**

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 a change in the limitations for sulphopropyl cellulose ion-exchange resin for the recovery and purification of proteins for food use. This action is in response to a petition filed by Life Technologies, Inc.

DATES: The regulation is effective (*insert date of publication in the Federal Register*); written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

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: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3071.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 22, 1996 (61 FR 37905), FDA announced that a food additive petition (FAP 6A4502) had been filed by Life Technologies, Inc., 8400 Helgerman Ct., Gaithersburg, MD 20874 (now, 9800 Medical Center

Dr., Rockville, MD 20850). The petition proposed to amend the food additive regulations in § 173.25(b)(5) *Ion-exchange resins* (21 CFR 173.25(b)(5)) to provide for a change in the temperature and pH limitations for sulphopropyl cellulose ion-exchange resin for the recovery and purification of proteins for food use.

In the notice of filing, published in the **Federal Register** on July 22, 1996, the agency announced that it was placing the environmental assessment (EA) on display at the Dockets Management Branch for public review and comment. No comments were received. On July 29, 1997, FDA published revised regulations under part 25 (21 CFR part 25), which became effective on August 28, 1997. These regulations established additional categorical exclusions for a number of FDA actions. As a result, such actions would no longer require the submission of an EA. Because the agency had not completed its review of the EA submitted with the petition, the agency evaluated whether a categorical exclusion under revised § 25.32(j) would apply to this rule.

After the filing of the petition on July 22, 1996, FDA determined that the petitioned amendment of the food additive regulations in § 173.25(b)(5) also necessitated an amendment of the provisions in § 173.25(d)(2), that provide extraction requirements for the ion-exchange resin. FDA published an amended filing notice in the **Federal Register** of August 28, 1998 (63 FR 46053), to announce this change. The amended filing notice also contained the agency's determination that the proposed action would not have a significant impact on the human environment, and therefore, that neither an environmental assessment nor an environmental impact statement was required. The notice, however, incorrectly cited the categorical exclusion under § 25.32(i), rather than the exclusion under § 25.32(j).

FDA published a final rule in the **Federal Register** of April 22, 1991 (56 FR 16266), that amended the regulation under § 173.25 to provide for the use of the ion-exchange resin and starting materials used to manufacture the sulphopropyl cellulose ion-exchange resin. The amendment to the regulation was based upon information provided in FAP 6A3905. In the final rule of April 22, 1991, the agency stated that while the sulphopropyl cellulose ion-exchange resin has not been

shown to cause cancer, it may contain small amounts of the starting materials, epichlorohydrin (ECH) and propylene oxide (PO), as byproducts of its production. Because the chemicals ECH and PO have been shown to cause cancer in test animals, the agency conducted a quantitative risk assessment to calculate the risk from the use of ECH and PO. Based on the results of the risk assessment, the agency concluded in the final rule of April 22, 1991, that there was a reasonable certainty of no harm from exposure to ECH (upper-bound limit of individual lifetime risk no greater than 8×10^{-15}) and PO (upper-bound limit of individual lifetime risk no greater than 1×10^{-14}) that might result from the proposed use of the additive.

As stated previously, FAP 6A4502 was submitted to amend the regulations in § 173.25(b)(5) and (d)(2) by changing the limitations for the temperature, pH, and the extraction requirements for the sulphopropyl cellulose ion-exchange resin. The petitioner did not propose any changes to the provisions under § 173.25(a)(20) for the manufacturing process, involving the starting materials ECH and PO, for the ion-exchange resin.

The agency has reviewed the information in the FAP's 6A3905 and 6A4502, and has determined that the information in FAP 6A4502 does not indicate a change in the manufacturing process. Therefore, the resin composition in FAP 6A4502 does not differ from the resin composition evaluated in the original petition (FAP 6A3905). Moreover, based on its evaluation, the agency finds that the proposed changes to the limitations for the temperature, pH, and the extraction requirements for the ion-exchange resin are expected to reduce the potential level of exposure to the residues of ECH and PO. Accordingly, the agency concludes that a recalculation of a risk assessment performed for the original petition FAP 6A3905 is not necessary to support this action.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe; (2) the additive will achieve its intended technical effect; and, therefore, (3) the regulations in § 173.25 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 determined under § 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 nor an environmental impact statement is 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 anytime on or before (*insert date 30 days after date of publication in the **Federal Register***), 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 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.25 is amended by revising paragraphs (b)(5) and (d)(2) to read as follows:

§ 173.25 Ion-exchange resins.

* * * * *

(b) * * *

(5) The ion-exchange resin identified in paragraph (a)(20) of this section is limited to use in aqueous process streams for the isolation and purification of protein concentrates and isolates under the following conditions:

(i) For resins that comply with the requirements in paragraph (d)(2)(i) of this section, the pH range for the resin shall be no less than 3.5 and no more than 9, and the temperatures of water and food passing through the resin bed shall not exceed 25 °C.

(ii) For resins that comply with the requirements in paragraph (d)(2)(ii) of this section, the pH range for the resin shall be no less than 2 and no more than 10, and the temperatures of water and food passing through the resin shall not exceed 50 °C.

* * * * *

(d) * * *

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(2) The ion-exchange resin identified in paragraph (a)(20) of this section shall comply either with:

(i) The extraction requirement in paragraph (c)(4) of this section by using dilute sulfuric acid, pH 3.5 as a substitute for acetic acid; or

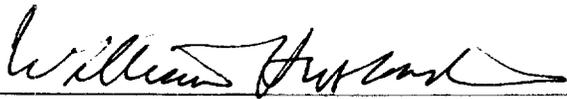
(ii) The extraction requirement in paragraph (c)(4) of this section by using reagent grade hydrochloric acid, diluted to pH 2, as a substitute for acetic acid. The resin shall be found to result in no more than 25 parts per million of organic extractives obtained with each of the

following solvents: Distilled water; 15 percent alcohol; and hydrochloric acid, pH 2. Blanks should be run for each of the solvents, and corrections should be made by subtracting the total extractives obtained with the blank from the total extractives obtained in the resin test.

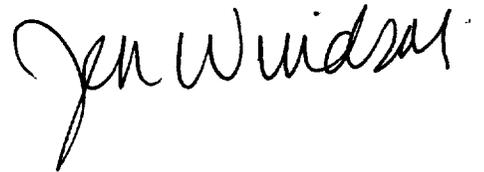
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Dated: MAR 17 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



William K. Hubbard
Acting Deputy Commissioner for
Policy



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