

delivery of educational activities and training; (5) maintains knowledge of information technology and learning standards as they apply to education and training to demonstrate and promote compliance and best practices by CDC programs; (6) applies the principles of instructional systems design and learning theory to design, develop, deliver, and evaluate informational and instructional products; (7) implements and maintains the CDC Training and Continuing Education Online web-based accreditation and registration system; (8) adapts information systems and processes to reflect current best practices and adherence to accreditation requirements; and (9) provides technical assistance and guidance to learners to ensure accreditation and learner support.

Delete in its entirety the title and functional statement for the Division of Training Development and Services (CPLD) within the Scientific Education and Professional Development Program Office (CPL), Office of Surveillance, Epidemiology and Laboratory Services (CP)

Dated: March 10, 2011.

**James D. Seligman,**

*Acting Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2011-6515 Filed 3-21-11; 8:45 am]

**BILLING CODE 4160-18-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-1991-F-0203] (Formerly Docket No. 91F-0111)

#### Hartech Corporation; Denial Without Prejudice of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is denying a food additive petition (FAP 1M4246) proposing that the food additive regulations be amended to provide for the safe use of a source of ionizing radiation to treat shellfish, including crustaceans.

**DATES:** This order is effective June 20, 2011; except as to any provisions that may be stayed by the filing of proper objections. Submit either electronic or written objections and requests for a hearing by April 21, 2011.

**ADDRESSES:** You may submit either electronic or written objections and

requests for a hearing identified by Docket No. FDA-1991-F-0203, by any of the following methods:

#### *Electronic Submissions*

Submit electronic objections in the following way:

*Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### *Written Submissions*

Submit written objections in the following ways:

*Fax:* 301-827-6870.

*Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### **FOR FURTHER INFORMATION CONTACT:**

Richard E. Bonnette, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1235.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of April 16, 1991 (56 FR 15373), FDA announced that a food additive petition (FAP 1M4246) had been filed by Hartech Corp. (formerly United States Harvest Technologies, Inc., One East Chase St., suites 1112 and 1113, Baltimore, MD). The petition proposed to amend the food additive regulations in § 179.26 *Ionizing radiation for the treatment of food* (21 CFR 179.26) to provide for the safe use of a source of ionizing radiation to treat shellfish, including crustaceans.

For any food additive petition, the burden is on the petitioner to submit to FDA data and information that are adequate for the Agency to determine that the proposed use of the additive under the specified conditions of use is safe (21 U.S.C. 348(c)(3)(A), 21 CFR 171.1). Hartech Corp. was notified of significant deficiencies in the information supporting its petition by letters from the Agency dated May 28, 1992, February 5, 1999, December 15, 2004, March 19, 2009, and May 22, 2009. The deficiencies related primarily to concerns about the possibility of *Clostridium botulinum* outgrowth in irradiated products, especially where the normal growth pattern of typical spoilage organisms could be changed by irradiation, thus reducing perception of spoilage. FDA had therefore requested information on typical spoilage and pathogenic microbial populations of shellfish irradiated at the maximum dose requested. FDA also requested additional data on the efficacy of the proposed doses of irradiation in reducing pathogens in crustaceans

because the petition only included data on the efficacy of irradiation in reducing the levels of *Vibrio* species in oysters.

Hartech Corp. has not provided information to address these deficiencies, and the Agency's most recent letters to Hartech Corp.'s last known address were returned as undeliverable. Additional efforts to contact this petitioner have been unsuccessful. The petitioner has not provided sufficient data and information for the Agency to conclude that the proposed use of the food additive is safe in accordance with section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348). FDA is therefore denying the petition without prejudice to a future filing (21 U.S.C. 348(c)(1)(B), 21 CFR 171.100(a)).

This order is effective as shown in the **DATES** section of this document; except as to any provisions that may be stayed by the filing of proper objections. Any person who will be adversely affected by this order may file with the Division of Dockets Management (*see ADDRESSES*) either electronic or written objections. 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. It is only necessary to send one set of documents. It is no longer necessary to send three copies of all documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the order may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the Agency has received or lack thereof in the **Federal Register**.

Dated: March 15, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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