DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1990–F–0390] (Formerly Docket No. 90F–0074)

Alpha Omega Technology, Inc.; 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 0M4181) proposing that the food additive regulations be amended to provide for the safe use of a source of irradiation to treat shellfish and finfish.

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 FDA–1990–F–0390, 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 March 15, 1990 (55 FR 9772), FDA announced that a food additive petition (FAP 0M4181) had been filed by Alpha Omega Technology, Inc., 1279 Route 46 East, Parsippany, NJ 07054. 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 irradiation to treat finfish and shellfish.

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). Alpha Omega Technology, Inc., was informed of significant deficiencies in its petition by letters from FDA dated May 28, 1992, September 15, 1993, February 10, 1999, July 20, 2004, March 19, 2009, and May 22, 2009. The deficiencies related primarily to the possibility of *Clostridium botulinum* outgrowth in packaged products, especially where the normal growth pattern of typical spoilage organisms could be changed by irradiation, thus reducing perception of spoilage.

FDA noted that the data provided in the petition indicated that there was very little margin of safety with regard to the concern for *C. botulinum* outgrowth and toxin elaboration, particularly in irradiated fish stored at temperatures between 46 and 50 degrees Fahrenheit. FDA therefore requested data demonstrating that products irradiated at the maximum dose requested and subjected to some temperature abuse would show evidence of spoilage before showing evidence of toxicity.

Alpha Omega Technology, Inc., has been unresponsive to these requests, and other efforts to contact the petitioner regarding the petition have not been successful. 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 (the FD&C Act) (21 U.S.C. 348). Consequently, FDA is 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.

[FR Doc. 2011–6623 Filed 3–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Food and Drug Administration/Xavier University Global Medical Device Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in co-sponsorship with Xavier University, is announcing a public conference entitled "FDA/Xavier University Global Medical Device Conference." This 3-day public conference includes presentations from key FDA officials and industry experts. The public conference has three separate tracks of interest for quality, regulatory affairs, and clinical research professionals, and is intended for companies of all sizes and employees at all levels.

Dates and Times: The public conference will be held on May 4, 2011, from 8:30 a.m. to 5 p.m.; May 5, 2011, from 8:30 a.m. to 5 p.m.; and May 6, 2011, from 8:30 a.m. to 1 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy.,

Cincinnati, OH 45207, 513–745–3073 or 513–745–3396.

Contact Persons:

For information regarding this notice: Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513–679–2700, ext 167, FAX: 513–679–2772, e-mail: *gina.brackett@fda.hhs.gov.*

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073, e-mail: *phillipsm4@xavier.edu.*

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 3 days of the conference. Early registration ends April 3, 2011. Standard registration ends May 2, 2011. There will be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES

Attendee	Fee by April 3, 2011	Fee by May 3, 2011
Industry	$995	$1,200
Small Business (<100 employees)	800	1,000
Academic	600	750
FDA/Government Employee	140	140

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the "Registration" link on the conference Web site at *http://www.XavierMedCon.com.* FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, e-mail, and payment information for the fee to Xavier University, Attention: Sue Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An e-mail will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th St., Cincinnati, OH, 45202, 513–421–9100. Special conference block rates are available through April 12, 2011. To make reservations online, please visit the "Venue/Logistics" link at *http://www.XavierMedCon.com.* If you need special accommodations due to a disability, please contact Marla Phillips (see *Contact Persons*) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will provide those engaged in FDA-regulated medical devices (for humans) with information on the following topics:

- Changes Within the Center for Devices and Radiological Health (CDRH) That Will Impact Our Industry.
- 510(k) Changes: Panel Discussion.
- Combination Products Panel.
- Update on Quality System Regulations. Warning Letter and Enforcement Action Trends.
- MDUFMA Legislation.
- Corrective and Preventive Actions.
- Clinical Data Requirement Changes—Premarket Clearance.
- Reimbursement Panel.
- MDR Reporting/Vigilance.
- Ethical Issues Leading to Non-Compliance In Clinical Trials.
- Risk Management and Design Controls.
- 510(k) SE Decision Making Process.
- Warning Letter Trends for Sponsor-Monitors and CRO's.
- Supplier Controls.
- Advertising, and Promotion and Labeling Pre- and Post-Market.
- Ensuring Site Compliance in Clinical Trials.
- FDA's Bioresearch Monitoring Program–Overview and Current Activities.
- Inspection Readiness.
- Training.
- International Regulatory Update.
- FDCA, Anti Kickback and False Claims Act, Implications of Investigator-Initiated Trials.
- Recalls, Requirements and Challenges.
- CE Mark.
- Adverse Event Reporting During Clinical Investigation in the EU.
- Clinical Evaluation for EU Market Access.
- Using Electronic Medical Records.
- Cooperative Research Activities Between Academia and Industry.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government agencies to small businesses.

Dated: March 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–6619 Filed 3–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Amended Notice of Establishment

Notice is hereby given as a correction in the announcement of the establishment of the NCI–Frederick Advisory Committee, which was published in the **Federal Register** on March 15, 2011, 75 FR 14035.

This FRN is amended to replace the word "Council" used in the second paragraph to the word "Committee".

Dated: March 16, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–6742 Filed 3–21–11; 8:45 am]

BILLING CODE 4140–01–P