



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

5600 Fishers Lane, HFS-681
Rockville, MD 20857

Date: SEP 06 2007

Subject: Registration of a Food Facility – Public Health Security and Bioterrorism Preparedness and Response Act of 2002

To: Responsible Official

The Food and Drug Administration has determined that your facility may be subject to the registration requirement in § 415 of the Federal Food, Drug and Cosmetic Act (the Act) and our implementing regulation at 21 CFR Part 1, Subpart H. The failure to register a facility as required is a prohibited act under § 301 of the Act. Our records indicate that, to date, this facility has not been registered with FDA.

As a responsible official of a facility that appears to manufacture/process, pack or hold food for human or animal consumption in the United States, you are responsible for ensuring that your overall operation and the products you distribute are in compliance with the law.

You may wish to go to <http://www.cfsan.fda.gov/~dms/fsbtbook.html> to obtain an on-line copy of "What You Need to Know about Registration of Food Facilities" or request a hard copy from the FDA Industry Systems Help Desk at 1-800-216-7331.

We request that the owner, operator, or agent in charge of this facility, or an individual authorized by this facility's owner, operator, or agent in charge, register the facility with FDA within 30 working days of the date of this letter. Registration may be accomplished on-line at <http://www.access.fda.gov>. We strongly encourage the use of electronic registration because it will result in an automatic confirmation of registration and automatic issuance of a registration number.

Alternatively, the owner, operator, or agent in charge of this facility, or an individual authorized by the facility's owner, operator or agent in charge, may register the facility by mail or fax (e.g., if you do not have reasonable access to the Internet) using FDA's food facility registration form, Form 3537. This form may be obtained by calling the FDA Industry Systems Help Desk at 1-800-216-7331 or 301-575-0156, or by writing to the agency at the following address:

U.S. Food and Drug Administration, HFS-681
5600 Fishers Lane
Rockville, MD 20857

When completed, the form may be faxed to (301) 210-0247 or mailed to the address above. FDA will process registrations submitted by mail or fax and provide a facility registration number using the same method used to submit the registration to FDA.

If you have already registered your facility, no other action is necessary.

Sincerely yours,

FDA Unified Registration and Listing and Prior Notice System Helpdesk