

SUBJECT: **FDA's New Food Bioterrorism Regulation: Interim Final Rule –** <u>*Registration*</u> of Food Facilities

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Secretary of Health and Human Services to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply. To carry out the provisions of the Bioterrorism Act, FDA published, on October 10, 2003, an interim final regulation, *Registration of Food Facilities*, which requires domestic and foreign facilities that manufacture/process, pack, or *hold* food for human or animal consumption in the United States to register with the FDA. Under this interim final regulation, all affected facilities must register by *December 12, 2003*. In the event of a potential or actual bioterrorism incident or an outbreak of food-borne illness, facility registration information will help FDA to determine the location and source of the event and permit the agency to notify quickly facilities that may be affected.

This new regulation pertains *only* to facilities that manufacture/process, pack, or *hold* food, as defined in the regulation, for consumption in the U.S. Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

Food contact substances and pesticides are not "food" for purposes of the interim final rule. Thus, a facility that manufactures/processes, packs, or holds a food contact substance or a pesticide is not required to register with FDA.

Facilities can register online via the Internet, by completing a paper form, or submitting to FDA a CD-ROM with relevant registration information. The online registration system will be available for use on *October 16, 2003*. For assistance with online registration: in the U.S call 1-800-216-7331 or 301-575-0156; from elsewhere call 301-575-0156; or send a fax to 301-210-0247. Requests for assistance also may be emailed to furls@fda.gov. Beginning October 16, 2003, the Online Registration Help Desk will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time. Also, you may refer to the attached question and answer fact sheet.

Customs and Border Protection contacts for the implementation of the FDA Bioterrorism Act are Dave Berry, Port Director, Huntsville @ 256 772-3404 or Howard Hodes, Supervisory Import Specialist, New Orleans @ 504 670-2161.

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