



**SNACK FOOD
ASSOCIATION**
An International Trade Association

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VIA Electronic Mail and by Hand

April 2, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0276

**RE: Implementing Regulations of PL 107-I 88:
Docket No. 02N-0276, Section 305 (Registration)**

Dear Sir or Madam:

The Snack Food Association (SFA) is an international trade association representing snack food manufacturers and suppliers. SFA business membership includes, but is not limited to, manufacturers of potato chips, tortilla chips, crackers, corn chips, pretzels, popcorn, extruded snacks, meat snacks, pork rinds, snack nuts, party mix, fruit snacks, cereal snacks, snack bars, and various other snacks. Retail sales of snack foods in the U.S. total more than \$30 billion annually.

SFA strongly supports a rigorous food security system to protect the nation's food supply. Last year during Congressional debate on food security, SFA supported the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. However, we are concerned about some provisions of the draft regulations put forward in the Federal Register on February 3, 2003 to implement the Act. Specifically, SFA appreciates the opportunity to respond to the request for comments on Section 305: Bioterrorism Preparedness; Registration of Food Facilities.

We would ask you to take the following into consideration in making amendments to the regulations prior to their finalization:

Definition of "Facility." FDA is proposing in Sec. 1.227(c)(2) to define a "facility" as "any establishment, structure, or structures under one management at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States." This definition of a "facility" is overly broad. It is common practice in the snack food industry to utilize very small temporary facilities for short-term product storage. These are locations that are

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used to temporarily store small amounts of product to be delivered to food stores, convenience stores, etc. within a short period of time. They may change very frequently as local needs change. Because these are very small holding facilities and may only be used on a temporary basis, it may be impossible to assure that all "facilities" are registered within the time that they are operational. An exemption must be considered for smaller size "temporary food storage facilities." SFA recommends that an exemption be granted based on square footage (e.g., less than 400 square feet).

Also, while the FDA has assured stakeholders in meetings that it was not its intention to have over-the-road trucks or delivery trucks register, this is not crystal clear in the regulations or preamble as presently drafted. The fact that trucks transporting food to warehouses, food stores, etc. need not be registered must be addressed in clear and unequivocal language in the final regulation.

Information Required in the Registration. FDA is proposing in Sec. 1.232 that registrants must submit to FDA certain information, including: The name, full address, phone number, fax number, and e-mail address of the facility (paragraph (a)); the name and address of the parent company (paragraph (b)), if the facility is a subsidiary of the parent company; emergency contact information, including the contact's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available) (paragraph (c)); all trade names the facility uses (paragraph (d)); and the name, address, phone number, fax number (if available), and e-mail address (if available) of the U.S. agent for foreign facilities (paragraph (f)). The information required, such as emergency numbers, etc. would be useful to facilitate communication between companies and FDA should an investigation become necessary.

The preamble further states that the emergency contact person does not have to be physically located at the facility; however he or she must be accessible and able to respond in an emergency. Thus, for example, a parent corporation can list as the emergency contact the name of an individual at headquarters who has overall responsibility for responding to emergencies at any facility owned by the parent company. SFA supports the FDA's proposal to allow a company to register all facilities through their headquarters and require only one emergency contact for that company.

Updates to Registration Information. FDA is proposing in Sec. 1.234 that the owner, operator, or agent in charge must submit a timely update to FDA via the Internet (or by paper copy if no Internet access) within 30 calendar days of any change to any of the information previously submitted, including, but not limited to, the name of the owner, operator, or agent in charge. Because the FDA is using the broad food categories in 21CFR170.3 and not requesting product codes, this does not appear to be overly burdensome for snack manufacturers. However, the requirement that updates must be filed within 30 days of a change could become burdensome if a manufacturer were to move to any of the other product categories, thereby triggering

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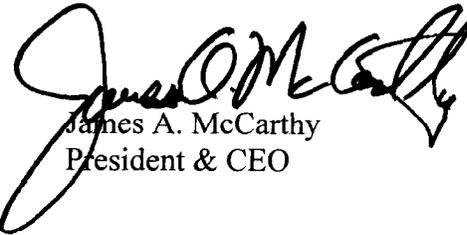
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re-registration. Thus, SFA is recommending semi-annual or annual updates be required in lieu of the 30-day update proposal.

We appreciate the opportunity to comment on this proposed regulation and are committed to working with FDA and all government agencies to protect the food supply.

If you have any questions, please do not hesitate to contact us.

Respectfully submitted,



James A. McCarthy
President & CEO