

## FLAVOR AND EXTRACT MANUFACTURERS ASSOCIATION OF THE UNITED STATES

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Dockets Management Branch U.S. Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

ATTN: Docket No. 02N-0276 (Registration)

On behalf of the Flavor and Extract Manufacturers Association of the United States (FEMA), I am pleased to submit comments on the interim final regulation: "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," (The Bioterrorism Act) 68 Fed. Reg. 58894 (October 10, 2003). FEMA is the national association of flavor manufacturers and represents the vast majority of flavor companies in the United States. FEMA members create flavors for use in a wide variety of food and beverage products.

We are utilizing this comment period to request clarification on the issue of disclosing facility registration numbers. Specifically, are companies with facilities registered with the FDA permitted to provide their facility registration numbers to customers, suppliers, brokers and other commercial partners that request it? Although The Bioterrorism Act and interim registration regulation clearly prohibit the FDA from disclosing any facility registration information, the sharing of registration numbers from private company to private company is not addressed. In the absence of guidance from FDA, some companies have decided to keep this information confidential, while others are sharing it with customers who request it.

We are not referring to any other information contained in the facility registrations or the PIN number used to manage the on-line accounts. We are referring only to the 11 digit registration number that is assigned to each facility.

FEMA is not suggesting any particular position for FDA to take on this issue other than to provide clear guidance one way or another. We have advised our members that in the absence of clear guidance from FDA their companies must decide individually whether or not to share this information and under what circumstances.

We appreciate the opportunity to comment on this proposed regulation. We are of course available to discuss any of this issue at your convenience.

Sincerely,

Glenn Roberts
Executive Director

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