



*Advancing Quality Healthcare
Through Over-the-Counter Medicines
and Nutritional Supplements*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

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Re: [Docket No. 02N-0276], Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5378-5427 (February 3, 2003)

These comments are submitted on behalf of the Consumer Healthcare Products Association¹ in response to the proposed regulations published in the February 3rd *Federal Register* Notice. [Docket No. 02N-0276], 68 Fed. Reg. 5378-5427 (February 3, 2003).

CHPA is generally supportive of the FDA's proposed regulation to implement Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereinafter "Bioterrorism Act"). In the wake of the terrorist attacks of September 11, 2001, Congress has mandated with great specificity that all facilities involved in the manufacturing, processing, packing or holding of food for consumption in the United States shall register with FDA. We recognize that the specificity of the law itself in many ways preordained the contents of these proposed regulations and leaves little flexibility to the agency. However, CHPA encourages FDA to re-consider its position with respect to the definition of food and the confidentiality afforded to the information provided to the agency.

1. For purposes of these regulations, the definition of a "food" should be narrowed to include only those articles that themselves are intended for consumption.

Section 305 of the Bioterrorism Act amends the Federal Food, Drug and Cosmetic Act ("FD&C Act") to require that all facilities involved in the manufacturing, processing,

¹ CHPA, founded in 1881, is the national association representing manufacturers and distributors of over-the-counter (OTC) medicines and nutritional supplements. Its membership comprises over 200 companies across the manufacturing, distribution, research, supply and advertising sectors of the self-care industry.

packing or holding of food for consumption in the United States shall register with FDA. 21 U.S.C. §350(d). FDA takes the position in the proposed regulation that “food” should be defined for purposes of this section in the same manner as “food” is defined in section 201(f) of the FD&C Act. 68 Fed. Reg. at 5382.

This expansive definition includes as “food” such items as raw agricultural commodities for use as food or components of food, dietary supplements and dietary ingredients. *See* proposed 21 C.F.R. §1.227(c)(4), 68 Fed. Reg. at 5418. Industry does not question that both finished dietary supplement products and their components (both active and inactive ingredients) are squarely within the meaning of “food” intended by Congress. CHPA further understands that facilities that manufacture both food and non-food articles (such as drugs or cosmetics) that have previously registered with FDA pursuant to other statutory or regulatory obligations would still be required to register as food facilities for purposes of the Bioterrorism Act. CHPA and its member companies appreciate their responsibilities and do not oppose dual registration for their mixed-use facilities.

However, using the definition of “food” in section 201(f) of the FD&C Act would also encompass “substances that migrate into food from food packaging and other articles that contact food.” 21 U.S.C. §321(f). CHPA believes that Congress did *not* intend that all food packaging materials, as well as machinery and equipment that come into contact with dietary supplements or other foods during their manufacturing and processing, should be considered as “food” for purposes of this registration requirement. CHPA respectfully requests that FDA re-consider its position with respect to these materials and equipment.

In Section 305, Congress refers to “food intended for consumption in the United States” as the criteria for requiring registration of food facilities. It is striking that Congress intended the law to apply to food *intended for consumption*, not for contact materials – like packaging or preparation surfaces – that are clearly *not intended for consumption*, and thus, are less likely to pose a bioterrorism risk from the manufacturing of the packaging or the contact material itself.

FDA’s ample authority in other areas of food regulation should not be overlaid onto the very specific requirements of facility registration and the purposes this law is intended to achieve. Clearly, the broader definition of “food” found in section 201(f) in the FD&C Act (that does apply to packaging and contact surfaces) is necessary for FDA to exercise its authority to protect public health when it performs plant inspections that might unveil contaminated preparation surfaces, unsanitary conditions for packaging of foods, etc. In contrast, this registration requirement is intended to allow FDA to maintain a registry of facilities likely to be impacted by the outbreak of a food-borne illness. It is unlikely that a facility that merely manufactures or holds the packaging material, cutlery or production line equipment that may later come into contact with food, would be targeted for an attack. Even so, under a narrower definition of food, FDA would still have immediate access to the actual manufacturer or packager of the food who would be able to alert its upstream

suppliers of the packaging and equipment, should such a situation ever arise that implicates the packaging or contact materials themselves prior to their coming into contact with food.

Therefore, FDA should narrow the definition of “food” in its proposed regulations governing the registration of “food” facilities to exclude those facilities that are involved in the manufacturing, processing, or holding of food packaging or food contact materials that are not themselves intended for consumption.

2. FDA should impose strict protection on the confidentiality of the information it receives pursuant to the food facility registration provision.

In the proposed regulations, FDA states that the information received from a food facility registration form is not subject to disclosure under the Freedom of Information Act. Proposed §1.243, 68 Fed. Reg. at 5420. However, at the public meeting held on January 29, 2003 to announce the release of the proposal, FDA officials stated that the information contained in those forms could be provided to other state or federal government agencies. There is no explanation as to why other agencies might have a need for this information, what conditions of confidentiality might be satisfied to permit the release of this information, nor whether they would be under the same obligation of confidentiality which FDA has imposed on itself. This announcement seems to undermine the protection Congress sought to provide for sensitive information. CHPA seeks assurances in the final rule that these issues will be addressed to assure that sensitive information such as emergency contact information (including home addresses and phone numbers) will be adequately protected if shared with other agencies.

CHPA and its members are eager to work with the agency to implement the requirements of the Bioterrorism Act in a manner that assures public health but imposes the least burdens on industry that are needed to carry out the mandates of the law. We appreciate this opportunity to provide our views to the agency on this important topic.

Respectfully submitted,



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