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DRAFT

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

**Re: Proposed Regulation for Registration of Food Facilities
FDA Docket No. 02N-0276**

These comments are submitted by the Paperboard Packaging Council (PPC), a national trade association representing producers of paperboard packaging, including packaging for food. The PPC also represents a wide range of companies that supply materials and accessories used in the manufacture of paperboard packaging. PPC members include integrated and independent paperboard producers, large and small companies, and companies with multiple production and storage facilities. PPC represents companies with facilities in the United States, Mexico and Canada, as well as other foreign countries. Virtually all of the packaging and packaging component facilities of the member companies would be impacted by the proposed regulation.

The registration regulation would impose an unreasonably heavy burden on PPC's member companies that is not justified by a corresponding increase in the safety of the nation's food supply. The proposed expansive application of the registration requirement contravenes the language of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") and FDA's mandate to ensure the safety of the United States food supply in the least burdensome means possible.

The Proposed Extension of the Registration Requirement to Food Packaging and Other Food Contact Substances is Contrary to the Language of the Bioterrorism Act

Section 305 of the Bioterrorism Act provides that the Food and Drug Administration ("FDA") shall by regulation "require that any facility engaged in manufacturing, processing, packing or holding food for consumption in the United States be registered [with FDA]." (Emphasis added.) Congress expressly modified "food" with the term "for consumption" in describing facilities that are subject to the registration requirement. FDA has ignored this explicit language and instead extended the proposed registration requirement beyond the intent of the law.

The FDA's proposed definition of "food" would encompass all articles within its statutory jurisdiction under 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), rather than limit the scope of the registration provision to "food for

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consumption.” FDA provides examples of products that are technically considered “food” under the FD&C Act, including “substances that migrate into food from food packaging and other articles that contact food.” 68 Fed. Reg. 5378, 5382 (February 3, 2003). Under this expansive definition, any facility engaged in the manufacture, processing, packing, or holding of any component or precursor substance of food packaging or any other food contact material would be required to register, because any component of a substance that may migrate into food is considered a “food” under FDA’s interpretation. However, none of these components or substances is “food for consumption,” and therefore Congress plainly did not intend such facilities to register. FDA’s approach ignores the well-established principle of statutory construction that each word in a statute must be given full effect.

Section 305 of the Bioterrorism Act states that FDA may, through guidance, require the category of food (as defined in 21 C.F.R. 170.3) to be included on the registration. No categories exist for food packaging or other food contact articles and their components. Because this statutory language cannot be given effect with respect to food packaging and contact materials, it is further evidence that Congress did not intend packaging and other food contact articles to be included in the definition of “food for consumption” for purposes of the registration requirement.

Congress instructed FDA to exercise “discretion in the development and implementation of registration regulations to ensure that registration requirements are neither burdensome nor disruptive of the smooth flow of commerce.” 148 Cong. Rec. H2858 (daily ed. May 22, 2002) (statement of Rep. Shimkus). Imposing the registration requirement on food packaging and food contact facilities violates this directive.

Applying the Registration Requirements to Food Packaging and Food Contact Materials Will Not Further the Purposes of the Bioterrorism Act

The stated purpose of the Bioterrorism Act, as expressed in the Conference report, is “to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.” H. R. Rept. No. 107-481, 107th Cong., 2d Sess., 107 (May 21, 2002). All requirements imposed by the Act therefore must be directed at achieving this goal. This goal will not be significantly advanced by imposing these requirements on food packaging and other food contact materials.

As explained by FDA in public meetings, one purpose of the registration requirement is to allow FDA to notify facilities engaged in a particular food sector of a threat to that sector. Robert Lake, FDA Satellite Video Conference (January 29, 2003). This stated purpose makes clear that the registration requirement should not apply to packaging and other food contact material facilities. In a case where FDA receives credible information of a threat to a particular food sector, FDA would notify the manufacturers. FDA would not attempt to identify the facilities engaged in the manufacture, processing, packing or holding of packaging, for to do so would be a waste of critical resources in time of crisis. Conventional food facilities necessarily maintain records regarding their suppliers, including packaging and other food contact material suppliers, and the processor would notify its suppliers or provide the information to FDA at the time of the incident. FDA need not maintain its own database of food packaging and food contact facilities.

It is highly unlikely that a terrorist attack or food borne illness outbreak would be propagated through packaging. In any event, packaging manufacturers and food processors have routine procedures in place to ensure that their packaging materials are

suitable for use with food, and would discover any possible threat to the food supply from packaging through these procedures. In the preamble to the proposed rule, FDA provides five examples of foodborne outbreaks that could be averted by the proposed requirements. The “vehicles” for these outbreaks are all conventional foods, and the examples bear no relation to packaging or other food contact articles.

In January 2002, FDA issued Draft Guidance for food establishments to implement security measures intended to protect the nation’s food supply. CFSAN, Draft Guidance: Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance (January 9, 2002). That guidance is directed at conventional food facilities. Packaging is mentioned merely as one of the items for which the conventional food facility should establish procedures. This guidance reflects the fact that food packaging is unlikely to be a source of a threat to the nation’s food supply, and demonstrates that imposing the requirements of the Bioterrorism Act on packaging will not advance the purposes of the Act. In FDA’s Final Guidance, announced in the Federal Register at 68 Fed. Reg. 13931 (March 21, 2003), FDA further separates “packaging” from “food,” mentioning packaging only in the Operations section. The Final Guidance recommends that a conventional food establishment develop procedures to ensure that “only known, appropriately licensed or permitted (where applicable) contract manufacturing and packaging operators” be used for food packaging and that food establishments inspect incoming materials, including packaging. Final Guidance, p. 10. FDA recognizes that packaging and food are two separate things. The approach taken in this guidance serves the purposes of the Bioterrorism Act in a much more tailored manner, recognizing that the likelihood of harm from packaging materials is minimal, and is best addressed at the time the materials are placed in contact with food.

The Economic and Administrative Burden on FDA and the Packaging Industry of Facility Registration Outweighs Any Potential Benefit to the Public

While the potential benefit of requiring registration for food packaging and contact materials facilities is slight, the burden and cost of such requirements, on the industry and on FDA itself, is immense, and cannot be justified. The regulations would apply to all facilities dealing with materials that might become a component of packaging or other food contact articles. Consequently, the requirements would apply not only to packaging producers, but also to their upstream suppliers and manufacturers of ingredients and components.

The difficulty with FDA’s expansive approach is highlighted by example. Under the regulation as proposed, all manufacturers of any form of paper product would be required to register because some of their material might be used to make food packaging. Because most facilities manufacture both food use and non-food use materials, registration would be required for the entire facility. Similarly, the entire chemical industry and all of their distributors would be included. Moreover, even curbside recycling programs would fall under FDA’s regulatory umbrella, for many food contact articles are comprised in part of recycled material. FDA’s expansive approach creates an excessive and unnecessary burden on both industry and the agency. Registration will be required for facilities in which most of the material handled will not contact food.

In estimating the cost of the registration requirement, FDA focused only on firms in a few key industries. Within these industries, FDA estimates that 22,000 facilities will be required to register. 68 Fed. Reg. at 5391. This estimate ignores entire categories and vast numbers of facilities that would be required to register under FDA’s unduly broad

definition of "food." This figure fails to include all "upstream" manufacturers of components of food packaging and contact materials, including the entire chemical industry, the paper industry, the recycling industry, and other such suppliers of precursor materials.

Further, FDA's use of estimates based upon amount of product used with food is invalid, for this fails to address the fact that the registration requirement applies to the entire facility, and therefore facilities that produce both food and non-food use products must register no matter what portion of their products end up as food use material. Because very few packaging facilities do not produce any food-use material, nearly all facilities operated by PPC members, and all of their suppliers, would need to register under FDA's proposed regulation.

FDA has also failed to consider the cost of the production time lost while these records are prepared, verified, and provided throughout the chain of distribution. Customers at every stage are likely to require verification all the way back up the supply chain that all required registrations are in place. Thus, although FDA has stated that each facility is responsible solely for its own registration, the realities of the marketplace demand that that the entire supply chain must be verified at each stage.

Conclusion

FDA's expansive application of the registration requirements to food packaging and food contact substances contravenes the language and purpose of the Bioterrorism Act, and supplies no benefit that could be justified in light of the tremendous burden this approach would create for both industry and the agency. Final regulations should clarify that, consistent with congressional intent, the registration requirements extend only to facilities involved with "food for consumption," and not to food packaging and food contact facilities.

Respectfully submitted,

A handwritten signature in black ink that reads "Jerry Van de Water". The signature is written in a cursive, flowing style.

Jerry Van de Water
President
Paperboard Packaging Council