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

**Re: Proposed Regulations for Establishment and Maintenance
of Food Records
FDA Docket No. 02N-0277**

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 regulations.

The recordkeeping regulations 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 recordkeeping requirements contravenes the purpose 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.

I. Applying the Recordkeeping Requirements to Food Contact Facilities Will Not Advance 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

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this goal. This goal will not be advanced by applying the recordkeeping provisions to food contact facilities.

It is highly unlikely that a terrorist attack or food borne illness would be propagated through food contact substances. Food contact materials manufacturers and food processors have routine procedures in place to ensure that these materials are suitable for use with food. Any possible threat to the food supply from packaging would be uncovered at this stage. In the preamble to the proposed rule, beginning on page 25225, 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.

As PPC has discussed in its comments on FDA’s proposals concerning the registration and prior notice requirements of the Bioterrorism Act, it is clear from the legislative history of the Act that Congress did not intend those requirements to apply to food contact substances. In light of those expressions of congressional intent, it is highly doubtful that Congress meant to impose recordkeeping requirements on facilities that would not need to register with FDA under the Act. If the burden of registration is not justified for food contact facilities, it is not logical to place the even greater burden of recordkeeping on these entities.

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, including food contact materials, is mentioned merely as one of the items for which the conventional food facility should establish procedures. This guidance reflects the fact that food contact substances are 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 food contact facilities will not advance the purposes of the Act. In FDA’s Final Guidance, announced by notice 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. Clearly, FDA recognizes that packaging, including food contact materials, and food are two separate things. The approach taken in this guidance serves the purposes of the Bioterrorism Act in a reasonable, tailored manner, recognizing that the likelihood of harm from packaging and food contact materials is minimal and that conventional food facilities play a large role in ensuring that the food contact substances they use are safe for food use.

Moreover, FDA has recognized the insubstantial risk posed by food packaging in excluding outer packaging from the scope of the recordkeeping requirements. FDA fails to provide any rationale for distinguishing the level of risk posed by food contact substances and outer food packaging, other than its conclusory statement that “the risk to human and animal health from contamination of outer food packaging is relatively small compared to the risk from

contamination of the immediate packaging that comes in direct contact with food.” 68 Fed. Reg. at 25190. Without an explanation, this unsupported distinction between the dangers posed by outer packaging and food contact materials appears to be arbitrary and capricious, in violation of the Administrative Procedure Act, and is patently insufficient to justify burdening the food contact industry with the substantial obligations imposed by the proposed recordkeeping regulations.

II. The Economic and Administrative Burden of Applying the Recordkeeping Requirements to Food Contact Facilities Outweighs Any Potential Benefit to the Public

While the potential benefit of requiring recordkeeping for food contact facilities is slight, the burden of such requirements on the industry is tremendous.

A huge number of potential food contact articles would be subject to the recordkeeping requirements under the proposed regulations. In addition to the broad array of materials FDA regulates in its food additive regulations, 21 C.F.R. Parts 170 through 189, the proposed rule would also extend to articles typically referred to as “housewares,” which are food contact articles such as plates, utensils, and cookware used in the home or retail establishments. These items have traditionally been considered outside the scope of FDA’s food additive authority, but are still defined as “food” under the FD&C Act. However, because FDA incorrectly applies an expansive definition of “food” for the purpose of triggering the requirements of the proposed regulations, all of these articles, and any of their components, would require recordkeeping.

Further, as currently drafted, FDA’s proposed regulations would extend to the wide range of “upstream” manufacturers that make ingredients and components that go into food contact articles. Any facility engaged in the manufacture, processing, packing, or holding of any component or precursor substance of food contact material would be subjected to the recordkeeping requirements, as any ingredient of an ingredient of something that may migrate into food is considered a “food” under FDA’s interpretation. For example, all of the distributors and suppliers of raw materials for the entire chemical industry would be included.

The extent of this burden is compounded by the fact that most manufacturers of food contact materials and their suppliers produce both food and non-food use products. Because a facility may not know at the time it ships a substance or material whether it is destined for food use, the facility will be compelled to establish and maintain records in order to ensure compliance with regulatory requirements in the event that the substance is in fact used for food at some point down the chain of commerce. This cautious approach will result in a tremendous waste of resources, perhaps leading to the establishment of records for every shipment of every chemical substance that might possibly have a food use.

The recordkeeping burden will be felt strongly by the many small independent establishments that handle food contact materials. These requirements are simply bad public policy as applied to the recycling industry, as many food contact articles make use of recycled input. The paperwork burden imposed by the proposed recordkeeping requirements would pose

a strong incentive for establishments to leave the business of turning recycled materials into food contact substances, as they simply would not have the resources to satisfy these requirements.

FDA attempted to narrow the scope of the recordkeeping proposal by excluding outer food packaging from the requirements. Given the practical realities of the packaging industry, however, this purported exclusion has little meaning. Nearly all packaging companies handle both outer packaging and food contact substances. FDA's assumption that half of the manufacturers and distributors of packaging handle only outer packaging materials (68 Fed. Reg. at 25212) may be true for suppliers in other packaging segments, is simply not correct when it comes to the cartonboard segment of the industry. Thus, packaging companies in our segment will find it more expedient to keep records on all materials -- both outer packaging and contact substances -- rather than to document only the food contact materials, because many of the same materials can be used for both purposes and it would be prohibitively expensive to segregate these uses. This would result in a recordkeeping requirement for nearly all facilities that manufacture packaging and packaging components, and all of their suppliers, under FDA's proposed approach.

Given the extraordinary burdens imposed by this proposal, FDA should focus on the area in which there is the opportunity to benefit the safety of the United States food supply -- conventional food itself. Under the proposed rules, conventional food facilities will be required to establish and maintain records concerning the food contact materials they receive and in which they will package food. This is the logical starting point for requiring recordkeeping concerning food contact substances, for this is the point at which any potential risk to the food supply from those substances would be posed. There is no benefit to applying the recordkeeping requirements to food contact facilities, and doing so amounts to nothing more than a waste of resources.

FDA has been tasked with an immense obligation, ensuring the safety of the United States food supply, and it must focus its attention on the sector where the expenditure of effort will yield returns in increased safety -- conventional food. 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 recordkeeping requirement on food contact facilities clearly violates this congressional instruction.

III. Conclusion

FDA's expansive application of the recordkeeping requirements to food contact facilities contravenes the express purpose of the Bioterrorism Act, and supplies no benefit that could be justified in light of the tremendous burden this approach would create. Final regulations should exclude food contact facilities from the scope of these requirements, consistent with FDA's appropriate exclusion of outer packaging, and require only that records of food contact materials be established and maintained by the conventional food facility that will place these materials in contact with food.

Respectfully submitted,



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