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

Via courier

Re: Comments on FDA's Notice of Proposed Rulemaking, "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Docket No. 02N-0277)

Purity Wholesale Grocers, Inc. ("Purity") submits these comments regarding FDA's Notice of Proposed Rulemaking, "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Docket No. 02N-0277), 68 Fed. Reg. 25188 (May 9, 2003).

Purity was founded in 1982, and is a \$1.5 billion wholesaler/distributor of dry groceries, as well as health, beauty care, and pharmaceutical products. Purity has business and distribution centers located in Lebanon, Indiana, and at other locations in the United States and Puerto Rico. In connection with its dry grocery wholesale/distribution business, Purity works with manufacturers, other distributors/wholesalers, and retailers.

Purity objects to the portions of the proposed regulations that would require it to establish and maintain records which reflect "[t]he lot or code number or other identifier of the food (to the extent this information exists)" and to any other portions of the proposed regulations that are intended to require Purity to establish and maintain records that track specific goods from an immediate previous source to an immediate subsequent recipient. For brevity, Purity will refer only to the lot or code number requirement in the balance of its comments, but these references, and Purity's objection, should be understood to also include any other requirement that Purity's records identify, for each particular case or pallet of food shipped to a customer, the supplier company from whom Purity received the case/pallet, and correspondingly for each particular case or pallet of

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food received by Purity, the company or companies to whom Purity shipped the case/pallet.

Although in some cases the lot or code number or other identifier of a food may literally *exist* for the foods Purity handles, it is not the case that the number is in all instances readily available to Purity or economically feasible for Purity to track. Moreover, this aspect of FDA's proposed regulations is not mandated by the language of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Act"), and any incremental security benefit that might be provided by such a requirement cannot outweigh the extraordinary burden placed on the distribution system, which will in turn, drastically drive up consumer prices and disrupt the present food supply.

Background – Industry Practice

By way of background, the current dry grocery distribution industry practice does not involve establishment and maintenance of records to track food received, released, or transported by lot (or other identifying) number. Instead, complete purchase and sales records are maintained in the company's books and records (either in electronic or paper form), from which purchasers, suppliers, and transporters of product can be readily identified. While Purity's records do not track lot numbers or otherwise identify, for each particular case or pallet of food shipped to a customer, the company from whom Purity received the case/pallet, Purity can nevertheless provide FDA with information sufficient to conduct a thorough tracing investigation. For any particular outgoing shipment, Purity can, using its records of incoming shipments, identify a subset of immediate previous supplier sources from whom Purity may have received the specific goods contained in the outgoing shipment. Similarly, for any particular incoming shipment, Purity can, using its records of outgoing shipments, identify a subset of immediate subsequent recipients who may have received goods contained in the specific incoming shipment in question.

The reasons that manufacturers' lot numbers (or other identifying numbers) are not utilized by distributors are simple: (1) there is no current requirement to track this information; (2) the information is generally not useful to distributors, who would handle a food recall by isolating *all* lots of the affected product and ceasing its further distribution in its entirety pending additional information from the relevant authorities; and (3) the food received by companies like Purity are occasionally not marked with lot numbers on their outer shipping cartons; and even if they are marked, they are not marked in any standardized way that can be read except manually.

With regard to the last item, where the outer shipping carton does indicate some identifying information, it often may do so in the form of a "closed" code containing lot and expiration information which requires deciphering. These "closed" codes are not standardized in any way, and as a result, cannot be routinely scanned by electronic reading devices. Purity can and does decipher the code in part, but only insofar as is necessary to perform a spot-check on expiration dating information therein to ensure that

the product being received is fresh, and to permit Purity to store the food appropriately, such that foods with shorter shelf-lives are distributed sooner than those with longer ones. This deciphering activity on the closed codes is only performed on a sample of the cases received, and is not performed on every case containing a code.^[1] Moreover, the fact that Purity stores the food it receives in part by reference to expiration date does not, in turn, necessarily translate into Purity storing foods by lot number – instead, Purity commingles different lots of the food it receives. For example, it may be the case that like foods (i.e., the same UPCs) from numerous different manufacturing lots are stored together in a single slot in Purity's warehouse because they share a common – such as a distant (e.g., 2006) -- expiration date. This co-mingling of product is industry standard practice.

The Economic Impact Of The Proposed Lot Tracking Requirements

In sum, Purity does not have, and to its knowledge, no other dry grocery food wholesaler/distributor has, ready access to the information that it would even need to begin to contemplate a system that would account for foods received and shipped by lot number. In the situation where there is no lot or other identifying information on the outer shipping carton, Purity would be required to open each and every case of food received to ascertain this information from the product. In some cases, incoming pallets from a manufacturer contain a single UPC; even where there is some lot information visible from the exterior of the pallet (i.e., you can see the lot number on some of the cases contained in the pallet), Purity would need to unpack the pallet in its entirety to confirm that each and every case on the pallet was from the same lot. Moreover, arguments could be made that Purity should also check that each case was accurately marked, and that the products within are from the lot so indicated on the outer shipping carton. At the end of the day, this essentially translates into a requirement that Purity hand-check every case of food on every pallet which it brings into its distribution center.

On a daily basis, Purity receives approximately 81 truckloads, which in turn contain approximately 2100 pallets comprised of approximately 290 types of different dry grocery products. If Purity is required to open each case contained on the 2100 pallets it receives daily and hand check the lot numbers for the products it receives, Purity estimates that its labor costs associated with unpacking its daily truckloads of incoming products would multiply by a factor of at least 15.

Even if Purity performed a less exhaustive check (for example, if it were permissible under the rules for Purity to assume that a pallet filled with a single UPC filled by a manufacturer with some visible lot numbers on the pallet represented the correct lot number for all cases on the pallet), just checking and manually recording that information alone could take anywhere from 30 minutes to 2 hours per truckload, depending on the number of different UPCs on the truck. The costs associated with this type of activity could double or even triple Purity's current labor expenses.

The labor costs associated with receipt of the foods is only the beginning of the economic impact for a food wholesaler/distributor like Purity. Purity would also be

required to store the food in different slots according to lot number in order to fulfill the corresponding requirement that the release or transport of food also be tracked by lot number. For example, 10 pallets of a particular food item (or a single UPC) may have come in to Purity from 3 different sources with 3 different sets of lot numbers. Under current practices, and assuming similar expiration dates, Purity will physically slot all 10 pallets in the same location within the warehouse, from which distributions will be made against particular orders placed. If Purity is required to maintain records which identify a lot number in connection with every food product that it releases, Purity would be forced to store identical foods with different lot numbers in separate storage slots to enable it to identify the specific lot number distributed. Thus, under the 10 pallet example above, Purity would be required to segregate the pallets in 3 different physical slot locations by lot number. This would in turn result in a requirement for exponentially more warehousing space and storage equipment, which translates into exponentially more warehousing expenses.

In addition, the lot tracking requirement would approximately triple Purity's costs associated with outgoing shipments. On a daily basis, Purity ships out approximately 115 truckloads containing approximately 2,283 pallets comprised of cases of approximately 1,051 different UPCs. There would be significant additional administrative and labor costs associated with new record keeping requirements to identify the multiple lot numbers of the various and numerous UPCs that are sent daily in fulfillment of given retail orders.

As FDA is well aware, the food distribution industry functions on extremely tight margins. The vast expense that would be required to achieve compliance with a lot number tracking requirement is not economically feasible. It may be the case in the future -- should lot information be standardized and made readily available on outer cartons, and with corresponding technological developments that would enable quick collection of this information in the files -- that the requirement proposed would not be unmanageable. But in the distribution world as it currently operates, the requirement imposes a prohibitive economic burden on distributors -- all without any mandate in the enabling legislation, and without any discernable improvement to food bioterrorism security measures.

The Act Does Not Require The Records That FDA Proposes

Nothing in Section 306 (or the balance of the Act) mandates a requirement for the tracking of lot numbers as FDA proposes. Similarly, the Act does not require establishment and maintenance of records that track specific goods from an immediate previous source to an immediate subsequent recipient. Instead, the Act only provides:

The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by person (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold,

or import food, which records are needed by the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

Section 306(a).

The Act's reference to "records are needed by the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food" can be fully satisfied by records identifying the immediate previous sources of all incoming shipments and the immediate subsequent recipients of all outgoing shipments. In sum, the requirement to track lot numbers and any related requirement that wholesalers/distributors' records identify, for each particular case or pallet of food shipped to a customer, the company from whom the wholesaler/distributor received the case/pallet, and correspondingly for each particular case or pallet of food received by a wholesaler/distributor, the company or companies to whom the wholesaler/distributor shipped the case/pallet, are not mandated by the Act. Indeed, Congress' use of the term "sources" and "recipients" instead of "source" and "recipient," suggests that FDA lacks the authority to mandate the greater detail that seems to be requested by the proposed rule.

The Benefit of the Required Records Does Not Outweigh The Burdens Imposed On The System

FDA has stated that lot number tracking is important because:

[it would] allow FDA the capability to limit its investigation to the implicated food. For instance, if a company repeatedly and consistently orders a particular food from a supplier, and the threat is associated with a single shipment or some shipments but not others, it is important to have the capability to isolate the shipment or shipments in question from others. This would be more cost effective and less burdensome for FDA. In addition, if the threat affects the transporter, identifying information such as lot numbers or other identifiers would facilitate the location and isolation of the conveyance that may have become contaminated by the implicated food. This cannot readily be done without information that specifically identifies the food.

68 Fed. Reg. 25188, at 25197.

In so stating, FDA fails to appreciate several significant policy considerations. First, FDA's use of lot numbers in this manner may in fact result in a greater threat to the public, as it carries with it the risk that FDA will cast too narrow a net when warning consumers and retailers and when conducting its investigation into potentially problematic foods. Historically, the retail food industry's reaction to problems (or potential problems) in the food supply has been the total cessation of distribution and sale

of any and all lots of the food in question, until it has been determined by the FDA that it is safe to proceed. There can be little question that this is a more cautious and protective way to cease and to resume distribution. Second, FDA fails to acknowledge that the extraordinary costs that will be incurred by those in the distribution system and will be passed on to consumers via the retail pricing of products. The burden of investigating multiple lots of potentially contaminated food versus a single lot is not so great to as impose this type of consequence on consumers – at least not until there is standardization in lot number marking and commensurate technology available which would make the tracking requirements economically feasible for those in the distribution chain. This is especially so when the costs associated with investigating potential problems with the safety of the food supply occurs – fortunately – only very infrequently, but the costs associated with implementing the lot tracking requirements will have effect on the food distribution business every minute of every day.

Conclusion

For the reasons stated above, we therefore respectfully request that the lot tracking requirements proposed in proposed Sections 1.337(a)(4) and 1.345(a)(4) be deleted in their entirety. Similarly, we request that the final rule not contain any requirement that a distributor's records identify, for each particular case or pallet of food shipped to a customer, the company from whom a distributor received the case/pallet, and correspondingly for each particular case or pallet of food received by the distributor, the company or companies to whom the distributor shipped the case/pallet.

Sincerely,



Bruce H. Krichmar
Director of Compliance

¹¹ For example, on a truckload containing between 1600-1800 cases, approximately five to ten cases will be so checked, depending on the number of different UPCs on board.