NACDS
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

July 8, 2003

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

Subject: Establishment and Maintenance of Records under Public Health Security and Bioterrorism Preparedness Act of 2002

To Whom it May Concern:

The National Association of Chain Drug Stores (NACDS) is responding to the proposed regulations that would require entities, such as chain pharmacies, that transport, hold, distribute and sell food, to store and maintain extensive "pedigrees" (records) of the source of and transportation process used for these food products.

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NACDS represents more than 200 chain pharmacy companies that operate nearly 35,000 community retail pharmacies. The majority of the NACDS membership consists of traditional pharmacies that are primarily in the business of providing prescription medications and health care products and services. Many of these members also sell food products, nutritional supplements, vitamins, refrigerated perishables and infant formula in their stores. About seven percent of traditional chain pharmacy's business is in food and related product sales. Some of our members are supermarket pharmacies and mass merchandise stores that also have pharmacy departments. These entities sell a more significant amount of food as part of their business. The proposed maintenance of records requirement would have a significant impact on all of our membership.

According to the rule, our members would be considered to be both transporters and non-transporters of food. Some of our members receive these food and related products directly from a wholesaler, while some larger members have their own distribution centers and warehouses in which they hold food that is provided by the manufacturers before it is distributed by the chain's own transportation system to individual stores.

NACDS recognizes the need to protect the quality and integrity of the food supply. The FDA appears to be attempting to design a system that generates detailed pedigrees that would help identify any potential source of threat to the food supply, and "narrow" the extent to which a particular product or products would need to be recalled. While admirable, the agency appears to be creating an extensive pedigree system that would overwhelm the food distribution supply, and create added costs that would likely have to be passed along to consumers.

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Recording of Sales Information: It is not clear whether pedigree papers have to be kept at the retail level for food products that are delivered by a chain's own transportation systems or by any transporter for that matter. We would suggest that all pedigree records for products being shipped to a multi-unit store entity be stored and maintained at the chain's corporate office, or an off site location designated by the chain headquarters. This will create greater certainty that the records will be retained in an organized manner, and will facilitate the process of any recalls that might have to be initiated. We also believe that the rule should request contact information for multiple persons at the entity's distribution centers or warehouses, as well as its corporate offices in case the FDA needs to contact a representative of the chain about a potential issue.

Finally, it is important that the final rule require that upstream entities provide all the required information to downstream entities in the food distribution system. There is simply no way that distribution centers that receive and store food, and retail outlets that hold and sell food, can know or should be required to determine, many of the information items required under the proposed regulation. Thus, requiring that any information be passed through the system from the first point of distribution – preferably through electronic means – would seem to alleviate some of the burden of the record keeping requirements on downstream entities.

Duplication of Registration Information: The proposed regulation appears to require that all entities (transporters and non transporters) in the food distribution system maintain extensive information that will already be on file with the FDA. Since the agency will already have the names and relevant contact information on transporters and non-transporters of food, it seems duplicative and a waste of resources to require distribution centers, warehouses, and retailers to have to record this extensive information each and every time a food shipment is delivered or sent.

Lot-Level Tracking: Currently, if a shipment of food is delivered to a warehouse facility, certain information can be maintained about the shipment, such as when it arrived and the person or entity transporting the products. However, our understanding is that lot-level tracking does not occur at the warehousing point of distribution. There can be many lots on a single truck, and many truck shipments coming in at the same time. These shipments are then stored in warehouses and are generally not segregated by lot numbers on the warehousing shelves, making it more difficult to create a system that tracks lot numbers of products as they are transported to other retail facilities. According to the proposed rule, however, transporters have to track lot numbers and specific brands of products, creating incredibly burdensome physical space issues and administrative tasks for chain distribution centers that are shipping products to retail outlets. This does not currently occur, and would result in significant costs in designing new systems to accomplish this goal.

Ingredient Tracking: The proposed regulation indicates that pedigree papers would have to include information "reasonably available to you to identify the specific source of each ingredient that was used to make every lot of finished product." That is, pedigree papers would have to be provided regarding the source of the actual ingredients that went into the production of each of these finished products. Such a record keeping requirement would be extremely detailed and almost impossible to accomplish, given that there are thousands of food and other related products on retail shelves. Some products – such as vitamins and nutritional supplements – may have dozens of ingredients, including some likely inert ingredients. Is it really the intent of the proposed regulation to require this level of tracking for each and every ingredient back to its source?

Moreover, the task is even more difficult to comply with given that the agency creates a subjective standard of "reasonably available" regarding this information. Is it acceptable for retailers to accept documents about similar products (i.e., two different brands of cookies) that have different levels of detailed information if one manufacturer says such information is reasonably available, while the other says it is not?

Information Services Infrastructure: A new information infrastructure would have to be created to support the scope and nature of the extensive records that the regulation would be required to be maintained relating to food. That is, there is no food distribution chain information system in place that would help facilitate the recording, exchange, or retrieval of information required under this regulation. Moreover, such tracking systems do not exist at the distribution center level. That means that until such infrastructure exists – assuming it is affordable to purchase for many of our members -- these records (i.e. lot number, quantity of the item, form of packaging, etc.) will have to be recorded and maintained manually, requiring many additional personnel that will spend thousands of hours recording this necessary information. Moreover, it appears that the scope and nature of the information required to be maintained under the proposed regulation is highly duplicative. That is, many distribution points have to maintain the very same information. This is highly inefficient, and will add costs to the distribution of food, which may have to be passed on to consumers.

Records Format: We support the provision that allows the records to be maintained either in electronic or paper formats. We believe, however, that the proposed retrieval requirements for these records should be changed to allow the records to be retrieved within 48 hours of the request. Expecting firms to provide records within 4 hours of a request appears to be unreasonable. Given that not all firms will be able to physically store paper records on site, they may have to use off site storage areas that may require more time to retrieve. In fact, given the fact that the proposed rules would require extensive records to be maintained for 2 years for almost all food products, it is highly likely that such records would have to be stored off site.

Implementation: We urge significant changes to these regulations that would reduce the burden on food transporting and selling establishments. While we agree with the goal of assuring the safety and quality of the food supply, these rules would add costs far outweighing their benefits. We further believe that the implementation date for this regulation should be extended by one year for each entity group (i.e., at least 18 months for large businesses, at least two years for small businesses, and at least 36 months for very small businesses.) However, the agency may want to consider a longer single implementation timeline for compliance by all entities – rather than a staggered implementation - to reduce the potential for implementation problems resulting from the fact that some suppliers might have to comply at one point in time while others do not.

We appreciate the opportunity to submit comments on this proposed regulation, and appreciate your consideration of our views.

Sincerely,

John M. Coster

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Facsimile Cover Sheet

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Comments:

Attached are comments on the Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 - Docket No. 02N-0277; RIN 0910-AC39.

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