June 19, 2003

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

Re: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Docket No. 02N-0277

Dear Sir or Madam:

Restaurant Depot Enterprises, Inc. appreciates this opportunity to submit comments to the Food and Drug Administration (FDA) regarding the proposed rule referenced above.

Restaurant Depot Enterprises, Inc. is a cash & carry wholesaler that supplies food and non-food product to restaurants. We are a vital component of the small independent restaurant supply chain as we keep a lot of the smaller restaurants in business when they cannot make minimums from their distributors, and they fill in with us on weekends when the distributor is closed for business. Customers purchase their product from us in the same manner they would from a supermarket or retailer. Restaurant Depot Enterprises consists of 22 warehouses and sells in excess of $700 million of food and retail products.

We are deeply concerned that some of the proposed recordkeeping and records access requirements will place unnecessary and impossible burdens on our business. We also urge FDA to make the following changes in the final rule and otherwise clarify certain outstanding issues:

1. **FDA should revise the record keeping requirements vis-à-vis "cash and carry stores."**

   As we operate a business that is essentially the same as any other retailer (although we sell to restaurants), our customers are rung up through a checkout register. As such, we do not keep detailed records of individual items purchased by customers. Requiring us to keep such records and not requiring retailers to keep such records would be patently unfair.

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2. The specific information required to be retained should not go beyond what is necessary for FDA to conduct a tracing investigation.

Requiring us to keep records about the transporter that delivers food to it is unnecessary and unreasonable as such records are not currently maintained by most distributors.

3. Requirement to retain "the lot or code number or other identifier of the food (to the extent this information exists."

It needs to be noted by the FDA that not all manufacturers/processors generate lot numbers for their products. Furthermore, no industry standard for lot numbers exists and, as such, they vary tremendously in form, including but not limited to, whether and where they even appear on product packaging. A cursory review of the product in our cash & carry locations shows that many of the items in both the outer case and inner case do not even have lot numbers. We are further disadvantaged as we sell product by both the unit and case, and there may be a lot number on the unit, but not on the case or vice versa. Furthermore, even if there was a lot number, it would be an impossibility to ring up the lot number of every single item purchased in addition to the UPC #. As a result of the above, we track incoming food by purchase order number, a far simpler and more efficient method. All foods have a purchase order and purchase order number. Restaurant Depot Enterprises, Inc. urges FDA to permit the purchase order number to serve as an acceptable identifier.

It should also be noted that the industry is moving to radio frequency identification technology (RFID) which should allow for much better tracking of product through the supply chain, as this gets rolled out in the next few years this should ease the FDA concern. Putting an impossibly onerous and non-workable system (from a practical standpoint as discussed above) in place today and then having to revamp it completely in the next few years would add just another level of burden on the industry, which is already suffering.

4. FDA should allow more time to produce records in response to a request.

The proposed rule sets very short time frames within which companies are required to make records available to FDA in response to an official request. A hard-and-fast-four hour timeframe is patently unreasonable. While records can be retrieved quickly in an emergency, a 4-hour deadline during normal business hours (or an 8-hour deadline outside of normal business hours) is not feasible. We strongly urge FDA to provide that companies must provide records access in a reasonable period of time.

5. Imposition of Criminal Liability

This section is, in our opinion, absolutely unreasonable. We are professionals managing a Company and we do not do any manufacturing of our own. Imposition of criminal liability would be inappropriate and excessive. We understand the need for information and compliance, but we cannot subject ourselves to criminal liability if we can show that we have performed to the best of our abilities.

Sincerely,

Richard Kirschner
Chief Operating Officer

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