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BY HAND DELIVERY

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

Re: **Docket No. 02N-0276**

Dear Sir or Madam:

Hyman, Phelps & McNamara P.C. appreciates this opportunity to submit these comments in response to the Notice of Proposed Rulemaking (NPRM) for Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The NPRM was published in the Federal Register of February 3, 2003, 68 Fed. Reg. 5378. We submit these comments on behalf of a large U.S. food manufacturer.

This letter focuses on a single topic—the need for an exemption from the food facilities registration requirement for certain small storage units used by salespersons and distributors. We first explain the background and need for this exemption and then suggest language to amend proposed 21 C.F.R. § 1.226 to include an exemption for this discrete class of incidental storage units.

02N-0276

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Background

Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002¹ (Bioterrorism Act) mandates that, by December 12, 2003, certain facilities that manufacture, process, pack, or hold food for consumption in the United States register with the Food and Drug Administration (FDA). Section 305 of the Bioterrorism Act defines a “facility” as “any factory, warehouse, or establishment . . . that manufactures, processes, packs, or holds food.” Bioterrorism Act, 116 Stat. 1667.

Under the proposal, registrants will be required to submit a variety of specified information, including the name and address of the facility, the name and address of the parent company, emergency contact information, and a list of all of the food product categories, as specified in FDA regulations at 21 C.F.R. § 170.3, handled by the facility.² If any required information changes, the registration will need to be updated within 30 days of the change. See proposed 21 C.F.R. §§ 1.232 and 1.234.

Consistent with the mandate of the Bioterrorism Act, FDA has included certain exemptions from the registration requirements in proposed 21 C.F.R. § 1.226. That section would exempt from registration certain foreign facilities that do not actually export to the U.S.; fishing vessels that harvest or transport food, or conduct certain limited food processing functions; farms; retailers; restaurants; nonprofit food facilities such as food banks and soup kitchens; and certain facilities regulated by the U. S. Department of Agriculture.

Notwithstanding the broad definition of “facility” contained in the Bioterrorism Act, the FDA has clear authority to provide for additional (discretionary) exemptions where appropriate, particularly where the burdens of regulation will yield trivial or no value. Environmental Defense Fund v. EPA, 82 F.3d 451, 466 (D.C. Cir. 1996); Alabama Power Co. v. Costle, 636 F.2d 323,360-61 (D.C. Cir. 1979) (“Categorical exemptions may also be permissible as an exercise of agency power, inherent in most statutory schemes to overlook

¹ Pub. L. No. 107-188, 116 Stat. 594.

² Although proposed 21 C.F.R. § 1.232 expressly requires all registrants to provide food product category information, the sample registration form published in the NPRM does not include food category information for facilities that are exclusively storage facilities.

circumstances that in context may fairly be considered *de minimis* . . . Courts should be reluctant to apply the literal terms of a statute to mandate pointless expenditures of effort.”); See also Monsanto Co. v. Kennedy, 613 F.2d 947, 955-6 (D.C. Cir. 1979); Cf., Federal Food, Drug, and Cosmetic Act (FDCA), § 309 (21 U.S.C. § 336). We believe extending the reach of the registration requirement to the small storage units described in the next section of these comments is such a *de minimis* situation.

It is important to note that, in addition to the registration requirements, Section 306 of the Bioterrorism Act includes a recordkeeping provision. Under that provision the FDA is authorized to promulgate regulations to require firms that “manufacture, process, pack, transport, distribute, receive, hold or import food” to establish and maintain records which “identify the immediate previous sources and the immediate subsequent recipients of food.” Under these recordkeeping regulations (which will be subject to a separate rulemaking), food manufacturers and suppliers will be required to maintain records of the recipients of their products, including salespersons and distributors, in order to establish traceability in the event of a threat to, or contaminant in, the food supply.

The Need for a Small Storage Unit Exemption

It is quite common for a food manufacturer or supplier to ship its products to salespersons or distributors throughout the United States. In many instances, the food is shipped to hundreds of salespersons or distributors. Many salespersons and distributors own, lease, or maintain a storage unit or storage room where product is held prior to sale, often for very brief periods of time. Generally these units or rooms are small—often less than 750 square feet.

These small storage units or storage rooms are unlikely to be the target of a bioterrorist attack or the object of surveillance or inspections by FDA. Should FDA obtain information regarding a possible threat relating to certain products, some of which may be stored in such a unit or room, the logical step for FDA would be to contact the manufacturer or supplier, not to try to communicate with each individual salesperson or distributor. Even in the event of suspected foodborne illness unrelated to terrorism, it is highly unlikely that the FDA would elect to contact all persons at the local sales/distribution level based upon its registration database rather than relying on the manufacturer or supplier to do so. In addition, it is unclear that FDA would have the resources or staffing to, itself, initiate contact at the local salesperson or distributor level. Communication from FDA relating to product should be directed to the manufacturer or supplier of that product, who will possess up-to-date contact information at the sales/distribution level, and will be in a position to take immediate, appropriate action.

Indeed, as noted above, under the recordkeeping requirements of the Bioterrorism Act, companies will be required to maintain records of the "immediate subsequent recipients" of their products, which would include local salespersons/distributors.

In contrast, registration of these small storage units or rooms will be very burdensome and time consuming for industry, particularly for individual sales representatives or distributors unaccustomed to navigating federal regulatory requirements. In addition, these registrations will require constant updating as new salespersons or distributors are appointed, storage locations change, new products are added, or other "reportable" changes are made. Further, it seems unlikely that FDA will derive any benefit from cataloguing and maintaining this vast array of information regarding these locations. On the contrary, this exercise will likely divert scarce agency resources away from other activities that would help safeguard the country's food supply.

Suggested Exemption Language

Consequently, we urge FDA to adopt in the final regulation a narrowly tailored exemption for small storage units or storage rooms used by salespersons or distributors. We suggest that the following paragraph (h) be added to 21 C.F.R. § 1.226 (the exemption Section):

- (h) A storage unit or storage room that is owned, leased, or maintained by a salesperson or distributor, if each of the following requirements is met:*
- (1) the floor space of the unit or room does not exceed 750 square feet;*
 - (2) the food stored in the unit or room is sold or supplied to the salesperson or distributor by a manufacturer or supplier who is registered under this subpart; and*
 - (3) the salesperson or distributor does not own, lease, or maintain any other facility that is exempt from registration under this paragraph (h).*

Importantly, this exemption language requires that the manufacturer or supplier of the products involved be registered. This requirement insures that FDA will be able to contact the manufacturer or supplier in the event of an emergency. The language also makes clear that a salesperson or distributor may not use more than one storage location that is exempt under this provision.

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We support the FDA's efforts to quickly implement a system to help guard the U.S. food supply from the threat of bioterrorism. However, we urge the FDA to adopt this exemption from registration for small storage units or rooms to avoid burdening industry, and in particular salespersons and small distributors, with a requirement that will provide de minimis benefit to public health and safety.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'M.D. Bernstein', followed by a horizontal line extending to the right.

Hyman, Phelps & McNamara, P.C.

By: Michael D. Bernstein

MDB/vsf