



Shaklee Corporation

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July 3, 2003

VIA FEDERAL EXPRESS

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

Re: Docket # 02N-0277, Establishment and Maintenance of Records;
Implementation of the Bioterrorism Act of 2002

Shaklee Corporation ("Shaklee") is a direct selling company that develops a variety of nutritional supplement and food products marketed through a network of thousands of independent distributors throughout the United States who operate home-based businesses selling Shaklee products. Shaklee submits these comments on the proposed regulations to implement section 306 of the Bioterrorism Act of 2002 on record maintenance and inspection in order to address the potential impact of the proposed regulations on its distributors as well as the millions of other individuals who participate in direct selling businesses selling pre-packaged nutritional products.

The proposed regulations as currently drafted would require millions of individuals who sell pre-packaged nutritional products through direct selling organizations to maintain records concerning their incoming shipments, which would be largely duplicative of records kept by direct selling companies. Moreover, hundreds of thousands of these individuals would also have to keep extensive records concerning their sales to individual customers. Such a result was neither intended nor mandated by Congress in the Bioterrorism Act, and would pose a considerable burden on the millions of individuals who have home-based businesses selling vitamins and other nutritional products.

I. The Structure of Direct Selling Companies

Direct selling is a popular model for distributing nutritional supplements. Unlike traditional retailing where products are sold to the general public through retail outlets, in a direct selling business products are marketed through networks of individuals, which fosters a personal relationship with the customer. Many of those engaged in direct selling of nutritional products are in the business part time. For seniors, stay-at-home parents, and others, direct selling businesses provide the opportunity to work a few hours on a flexible schedule, giving them a modest – but often very important – additional source of income.

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There are numerous variations of the direct selling model, but the structure of Shaklee's direct selling business is not uncommon. Shaklee independent distributors use their network of personal contacts to develop a customer base. Most of these customers sign up as Shaklee members, entitling them to discounts on product purchases. Many Shaklee independent distributors not only sell product to consumers, but recruit new distributors into their organizations. They assist these new distributors with the development and growth of their businesses.

Shaklee develops and manufactures the products and ships them to its independent distributors and, under the proposed regulations, will maintain records regarding these shipments. Most Shaklee distributors carry small inventories of product that they sell to local friends and neighbors. Many of these distributors also sell small amounts of inventoried product to other distributors from time to time to help them fulfill customer orders. Other distributors do not maintain inventory and place orders from Shaklee as needed to fill customer orders. In some cases, Shaklee ships products directly to the end consumer.

The distribution system is a closed system. Shaklee product flows from Shaklee through its independent distributors to consumers. All of the independent distributors are under contract with Shaklee. Distributors are not authorized to sell Shaklee product outside this system (e.g. to a retail store or to a non-Shaklee distributor).

II. Distributors for Direct Selling Companies Should Be Excluded from the Record Maintenance Requirements

Shaklee's independent distributors – and the distributors for other direct selling companies marketing nutritional products – should be exempt from the recordkeeping requirements with respect to both immediate previous sources and immediate subsequent recipients. Such an exemption is consistent with the requirements of the Act and is necessary to avoid placing unneeded and highly burdensome recordkeeping requirements on the millions of individuals who would otherwise be subject to these requirements.

Section 414 of the Federal Food, Drug & Cosmetic Act, added by section 306(a) of the Bioterrorism Act, does not mandate recordkeeping requirements. Instead, it permits the Secretary to establish recordkeeping requirements at his discretion. Even if section 306(d) of the Bioterrorism Act could be interpreted to mandate regulations rather than simply setting a timeframe for the finalization of any regulations implemented at the Secretary's discretion, the Act does not specify the content of the regulations. With the exception of farms and restaurants, which are statutorily excluded from the record maintenance requirements, the Secretary has full discretion to determine who shall be required to maintain records and what records shall be kept. Congress did, however, plainly communicate its intention to protect small business by stating: "The Secretary

shall take into account the size of the business in promulgating regulations under this section.”

A. Distributors for Direct Selling Companies Should Be Exempt from the Requirement to Maintain Records Concerning Immediate Subsequent Recipients.

In proposed section 1.327(d) of its draft regulations, FDA has relieved retailers of the burden of maintaining records regarding sales to individual consumers, acknowledging in the preamble that such recordkeeping would be unduly burdensome and is unnecessary to address threats of serious adverse health consequences to humans or animals. 68 Fed. Reg. 25188, 25192 (May 9, 2003). However, this exemption is limited to facilities that sell to consumers only. See proposed section 1.328 (defining “retail facility”).

In its current form, the proposed regulation would have a significant impact on the direct selling industry. As discussed above, many Shaklee independent distributors – like many distributors in the industry – sell product not only to consumers but also to other independent distributors in their network to support each others’ businesses and enable them to fulfill customer orders. Under the proposed regulations, many distributors for direct selling companies would be excluded from the exemption for retail facilities and consequently would be required to maintain records on every sale to a consumer.

This result is not required by the statute and would place a significant burden on hundreds of thousands of individuals. The vast majority of distributors in the direct selling industry work on their own, and most of them are engaged in the business on a part-time basis. The impact of the regulations on these very small businesses is exactly the type of impact that Congress required the Secretary to consider in enacting regulations.

Individual distributors for a direct selling company who sell to consumers should be permitted to transfer inventory amongst themselves without thereby disqualifying themselves from the recordkeeping exemption for retailers.

B. Distributors for Direct Selling Companies Should Be Exempt from the Requirement to Maintain Records Concerning Immediate Previous Sources.

In addition to exempting direct sellers from the requirement to maintain records on their sales to customers, FDA should acknowledge the unique, closed distribution model of the direct selling business in its regulations and exempt independent distributors in a direct selling organization from the requirement to maintain records concerning the immediate previous source.

In the closed distribution model of direct selling, the direct selling company is the source of all products sold by its distributors. Distributors typically obtain the products they redistribute directly from the direct selling company with which they are associated. Under the proposed regulations, the direct selling company will maintain records that identify the carriers and the distributors who are the immediate subsequent recipients of the product. Any records maintained by the distributor regarding the immediate previous source for such shipments would be wholly duplicative of the records held by the direct selling company.

As discussed above, in some cases, distributors will transfer inventory to other distributors in the direct selling organization to help them fill customer orders. Transfers between distributors occur entirely within the direct selling organization and typically involve small amounts of product that are transferred directly between distributors without the involvement a third-party transporter. While the total amount of product is not great, the transfers may occur with some frequency as needed to help other distributors fill customer orders, so maintaining records on each such transfer would impose a significant burden on individual distributors.

Unlike open distribution chains, where it may be difficult to trace food shipments unless all distributors touching the food maintain records, direct selling distribution chains are closed systems. That allows Shaklee, or any other direct selling company, to trace product through the system and contact its distributors quickly and directly in case of suspected adulteration. Therefore, mandatory recordkeeping by individual distributors would not substantially enhance FDA's ability to respond to incidents of food adulteration.

As discussed above, many of the individuals in the direct selling business are seniors or others who work part time to have an additional, often modest, source of income. These are precisely the types of very small businesses that Congress was concerned about when it directed the Secretary to consider the size of the business in proposing regulations. We anticipate that the burden of the recordkeeping requirement would cause many distributors to quit the business rather than comply with the regulations. Therefore, the requirement as proposed would have a significant impact on Shaklee's business as well as the overall nutritional product direct selling business.

FDA's economic analysis does not support the extension of the record maintenance requirements to distributors in direct selling organizations. FDA did not include direct selling businesses in its economic analysis of the proposed regulations. There are millions of individuals involved either on a full-time or part-time basis in the sale of nutritional products, so the estimated number of retail facilities (207,657) and wholesalers (95,745) relied on by FDA plainly does not include these individuals. The burden on these individuals will be higher than for other retailers, because they typically maintain small inventories and place orders more frequently, and because they are often

less sophisticated than traditional retailers. In addition, because of the very small scale of the business operations of direct sellers and the closed nature of the distribution system, the benefit of recordkeeping by these individuals is very small. For these reasons, the economic burden imposed on distributors in direct selling far exceeds the benefits of mandatory recordkeeping.

In view of the limited impact maintaining such records would have in securing public health and the burden recordkeeping would impose on these small businesses, individuals who distribute food products for a direct selling company should be exempt from the requirement to maintain records under the proposed rule.

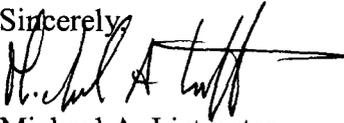
C. Proposal

The recordkeeping requirements should specifically address the direct selling model in proposed section 1.327 by providing that direct selling distributors are exempt from all requirements of proposed subpart J, except for sections 1.361 and 1.363. Only a full exemption for direct sellers takes into account the unique nature of this selling model and will relieve the millions of direct sellers of nutritional products in this country from burdensome recordkeeping requirements.

At a minimum, however, the language of the proposed regulations should be amended to ensure that direct sellers can take advantage of the more limited exemption proposed for retailers. This could be accomplished by revising the definition of "retail facility" so that it expressly includes all direct selling distributors. Alternatively, the definition could be amended by dropping the word "only," so that it would read: "Retail facility means a facility that sells food products directly to consumers." FDA could then clarify, either in the regulation itself, in the preamble, or in a guidance document that a direct selling distributor who sells inventory to another distributor for the same company does not thereby lose his or her status as a retail facility.

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Shaklee supports efforts to safeguard the nation's food supply, but encourages FDA to tailor its regulations to maximize their effectiveness while minimizing their impact on the millions of individuals engaged in direct selling of nutritional products.

Sincerely,

Michael A. Listgarten
Senior Counsel
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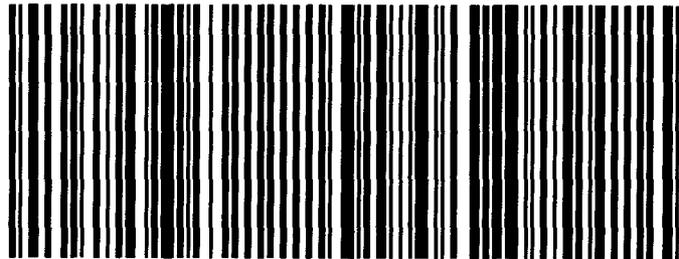
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