



Council for Responsible Nutrition

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

**RE: DOCKET 02N-0277, RECORDKEEPING REQUIREMENTS
UNDER THE BIOTERRORISM ACT**

The Council for Responsible Nutrition (CRN) is one of the leading trade associations representing the dietary supplement industry. CRN's member companies manufacture and market a large fraction of the leading dietary supplement ingredients and finished products, including national brands as well as store brands of vitamins, minerals, botanicals, and specialty products. CRN and its members are committed to taking appropriate steps to implement the requirements of the Bioterrorism Act of 2002, but we are concerned that FDA's proposed regulations in some respects are more burdensome than necessary to enable food producers to trace shipments of foods, including dietary supplements.

Persons Covered by the Rule: Need to Clarify Exemption for Sales Direct to Consumer

Some of CRN's member companies are engaged in marketing products directly to the consumer through direct sales, mail order, internet sales, and/or retail sales. The rule specifically exempts "retail facilities" from the recordkeeping requirement for tracing products directly to the "immediate subsequent recipient" when that recipient is a consumer. We urge FDA to clarify the scope of "retail facilities" to include independent distributors in direct sales forces, mail order companies, or internet sales operations, since it is apparent that neither Congress nor FDA intended for the recordkeeping requirement to encompass records of individual sales to consumers.

Applicability to Internal Transfers

Many of CRN's member companies are vertically integrated, with various facilities involved in the growing and processing of bulk ingredients as well as the manufacturing and marketing of finished dietary supplement products. Some of the requirements for recordkeeping could result in duplication of effort if each facility within the company is required to maintain separate records, even though the overall records are available at company headquarters or some central location. Clarification is requested regarding the level of recordkeeping that will be expected at each facility maintained by a vertically integrated company.

Identification of Transporters

As proposed by FDA, the rule would require nontransporters on both ends of a chain of custody to maintain records regarding the transporter that shipped the product from one company to the other. In general, the identity of the transporter is known to the shipper but may not be known to the receiver in this chain of custody. It is not reasonable to expect the receiver to have, seek, or maintain information on the identity and related contact information for the transporter that delivered the product, especially if multiple transporters may have been involved. Such information will more appropriately be available from the shipper that arranged for the transport. The current requirement would create enormous duplication, in that three parties would be responsible for documenting each transportation step (the shipper and the transporter, as well as the receiver).

Ability of the Company to Trace a Product *versus* Need for FDA to Trace a Product

FDA's proposed recordkeeping system is directed toward enabling *the government itself* to trace a product, rather than ensuring that *companies* are able to trace the product through all the links in the chain of custody of a food ingredient or product. CRN believes the intent of the Bioterrorism Act was to ensure the existence of a system that fully engages the institutional knowledge and logical procedures that already enable the companies responsible for the production and distribution of food to maintain an orderly and efficient nationwide supply chain and that also currently make it possible to effect rapid recalls when necessary.

The traceback records that are routinely established and maintained by food companies, including companies involved in the dietary supplement industry, are necessary to permit those firms to maintain and uphold due diligence duties to investigate potential product defects and promptly remove defective products from the market to prevent consumer injury. These records would appear to be entirely sufficient to meet the requirements of the Bioterrorism Act. FDA proposes instead to create a system that empowers the government itself to have direct access to private business information so that FDA itself can fully command the traceback investigation. CRN believes this proposal fails to capitalize on the efficiencies of time and resources available through effective public/private coordination, exemplified by the efforts that currently support effective recalls.

FDA estimates the costs of implementing its traceback system to be relatively low, based on the questionable assumption that the proposed requirements would not require substantial deviation from current industry practice. CRN believes the deviation from current practice is substantial and that it would result in large additional burdens and requirements that are not justified when the effectiveness of existing industry systems for responding to public health risks from adulterated food are already well established. The FDA proposal does not discuss the efficacy of the existing traceback system.

Timeline for Access to Records

FDA's proposal focuses on the timeframe for access to records, rather than on the timeframe for tracing the product. CRN and its members believe it would be more appropriate to put a time limit -- such as 24 hours -- on tracing and locating the product.

FDA proposes that access to records must be provided within four hours if the request is received during business hours, defined as 8:00 a.m. to 6:00 p.m., Monday to Friday. CRN and its members do not believe this is a reasonable requirement. If FDA chooses to require a timeframe for records access, as opposed to a 24-hour time limit for actually tracing and locating the product, as suggested above, then at least the timeframe should be longer -- perhaps eight hours -- and should be counted as eight business hours, not as eight hours on the clock. Naturally, in a genuine emergency, both FDA and the companies will be working as hard as possible to trace the product in question, using appropriate records, but as a matter of regulation there should not be a requirement that companies remain open until 8:00 or 10:00 p.m., for example, to honor a request received at 4:00 or 6:00 p.m., in cases where it may not be evident that there is any actual emergency to be addressed.

If the request is received outside of normal business hours, FDA proposes to require access to records within eight hours. This would suggest that a company must respond by 3:00 a.m. to a request received at 7:00 p.m. CRN does not believe this is reasonable. We suggest that FDA extend the limit to 18 hours, to permit personnel to be called to the facility at a reasonable hour and to have some time to produce the records. Alternatively, the limit might be set at eight or twelve business hours. A better approach, we believe, would be to restate the requirement as a 24-hour limit for actually tracing and locating the product, as suggested above. Again, in a real emergency, it would be expected that both FDA and the companies will be working as hard as possible to trace the product in question, inside or outside business hours -- but as a matter of regulation a reasonable response period should be provided.

Other issues are raised by the proposal. For example, in many cases, 8:00 a.m. to 6:00 p.m. will not be the normal business hours. A more typical business day for a headquarters facility would be from 9:00 a.m. to 5:00 p.m. We are assuming the relevant timeframe is the time zone of the company receiving the notification, but in the case of foreign manufacturers the person receiving the notification may be the resident agent and the company itself may be in Europe, Asia, or Australia -- six or twelve time zones away. Clarification is needed regarding the relevant timeframe in these cases.

Need for Procedural Safeguards

Under the Bioterrorism Act, FDA is authorized to require access to records only when these are necessary "to address credible threats of serious adverse health consequences of death to humans or animals." The scope of the records available to FDA is limited to those necessary to address such threats. The FDA proposal does not incorporate concrete, enforceable procedural safeguards to ensure that such searches conform with the law or with constitutional limits on government authority. Nor does the FDA

proposal include procedures or standards to ensure that there is no unauthorized disclosure of any trade secret or confidential information. Safeguarding consumer correspondence files and protecting the privacy interests of consumers also require specific consideration.

Conclusion

CRN appreciates the opportunity to comment on FDA's proposed rule on record-keeping requirements needed to implement the Bioterrorism Act. CRN and its member companies look forward to working with the agency to continue to ensure the safety of the food supply.

Sincerely,

A handwritten signature in black ink that reads "Annette Dickinson". The signature is written in a cursive, flowing style.

Annette Dickinson, Ph.D.
President