



Council for Responsible Nutrition

1875 Eye Street, N.W., Suite 400
Washington, D.C. 20006-5409
(202) 872-1488 • Fax (202) 872-9594
www.crnusa.org

August 30, 2002

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

**RE: Docket No. 02N-0277, Recordkeeping Requirements,
Implementation of Bioterrorism Act of 2002**

The Council for Responsible Nutrition (CRN) is submitting these initial comments on the recordkeeping requirements of the Bioterrorism Act of 2002, on behalf of its members in the dietary supplement industry. CRN represents a broad spectrum of the industry ranging from ingredient suppliers to finished product manufacturers, including both brand name products and private label products. Our member companies market their products in all distribution channels, including the mass market, natural food stores, multilevel marketing, and mail order. Our supplier members include companies that make or market all classes of ingredients incorporated into dietary supplements, including vitamins and minerals, amino acids, botanical ingredients, specialty products, and excipients.

CRN's member companies are committed to fully evaluating their procedures with regard to helping ensure that their facilities and products are secure from potential bioterrorism threats.

Our members' concerns about recordkeeping requirements are the same ones generally expressed by numerous associations in the conventional food industry. Some of these are summarized below.

- Need to permit utilization of existing recordkeeping systems, to the extent possible. Companies that manufacture, process, pack, transport, distribute, receive, hold, or import food are required to keep records identifying the immediate previous source and the immediate subsequent recipient of the food, including its packaging. CRN members believe they currently have in place the necessary records to permit such identification. We urge FDA not to require unique additional records for purposes of the Bioterrorism Act of 2002, but to permit companies to utilize existing records.

02N-0277

97

- Need for flexibility. Many companies may choose to use existing records such as invoices, bills of lading, and purchase orders to document the source and recipient of foods or ingredients they handle. However, it may also be the case that such records contain confidential or sensitive information. Therefore, some companies may choose to create a new record specifically for purposes of compliance with the Bioterrorism Act of 2002. CRN urges the agency to permit flexibility regarding a company's choice of the records it will maintain to document the source and recipient of foods or ingredients it handles.
- Comingling. As in other segments of the food industry, dietary supplement manufacturers may in some cases receive large shipments of ingredients that are combined into a single bin or container and then used in manufacturing a product. Thus, it may not be possible in all cases to identify a single source of each ingredient in a given batch of product. There may in some cases be two or more sources of the ingredient, and these of course can be identified. CRN urges the agency to recognize these practicalities.
- No need for lot tracing as required by drug regulations. The Bioterrorism Act of 2002 requires recordkeeping to facilitate tracking of product sources and recipients. This should not be interpreted as being equivalent to full lot tracing as required in drug manufacturing.
- Packaging. Information regarding the source of the packaging should be restricted to the food contact package.
- How long records must be kept. CRN members advise that they generally maintain records until one year past the expiration date marked on the product package. Most (but not all) dietary supplements bear an expiration date.
- Small business. While there are some very large corporations in the dietary supplement industry, there are also numerous small businesses. CRN urges FDA to make the recordkeeping requirements as straightforward and simple as possible, with appropriate flexibility to take account of different companies' systems and level of sophistication. Beyond that, we would not recommend a general exemption of small business, since this could in effect exempt a large fraction of the dietary supplement industry. Too large an exemption would fail to meet the need to enhance the industry's ability to trace potential public health problems to their source.

Thank you for the opportunity to submit initial comments on issues relating to the implementation of the requirements of the Bioterrorism Act of 2002. CRN and its members look forward to working with FDA to facilitate timely implementation and will avail themselves of every opportunity for interaction and comment as this process moves forward, in order to provide the agency with adequate information needed to address the many concerns that will arise. We will be pleased to respond to any specific questions FDA may have regarding the dietary supplement industry, to the best of our ability.

Sincerely,

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

Annette Dickinson

Vice President, Scientific & Regulatory Affairs