



## Council for Responsible Nutrition

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Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket No. 02N-0276, Registration of Facilities,  
Implementation of Bioterrorism Act of 2002**

The Council for Responsible Nutrition (CRN) is submitting these initial comments on the registration 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 will be impacted by the new requirement for registration of facilities in the same manner as other firms in the conventional food industry, and some of the concerns we share with the general food industry are outlined below. **In addition, we have a concern relating to the treatment of independent distributors in multilevel marketing companies.**

**Independent Distributors in Multilevel Marketing Systems Should Be Defined as "Retailers" for purposes of the registration requirement.**

CRN's members include several prominent multilevel marketing firms, including Nutrilite, Shaklee, Herbalife, GNLD, Mary Kay and the Unicity network. These companies market their products through independent distributors -- individuals who purchase products at wholesale from the parent company, for sale to consumers. These

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independent distributors function as “retailers” to the consumer. We do not have a good estimate of the total number of such individual independent distributors, but we are reliably informed that they number in the hundreds of thousands.

CRN urges that these individual independent distributors be defined as “retailers” for purposes of the registration provision of the Bioterrorism Act and thus be exempt from registration. The parent corporation’s manufacturing and distribution facilities will of course be registered, and there are provisions within each company for rapid communication between the corporation and its independent distributors (in both directions), should any problem arise involving the company’s products.

### **General Concerns CRN Members Share with the Conventional Food Industry**

- Who submits the registration for each facility? CRN encourages FDA to be flexible in permitting companies to determine where within the corporation the responsibility lies for registering all facilities. In most cases, corporate headquarters may wish to carry the burden of registration for all its facilities, in order to maintain adequate control and to ensure that all requirements are met in a timely manner and updated as needed. The centralization of responsibility for registration within a company is not incompatible with FDA’s likely intent to assign unique identification numbers for each facility.
- What is a facility? CRN also encourages FDA to permit some flexibility in defining a “facility.” If a corporation has multiple buildings with different purposes at a single site, does that represent a single facility? If a corporation owns adjacent buildings with different addresses but treats them as a single operation, can those be defined as a single facility? These are judgments perhaps best made by the corporation, provided the registration meets the need to adequately identify each location at which food is manufactured, processed, packed, or held.
- Desirability of maximum automation of the registration process. CRN urges the agency, as we understand it intends to do, to maximize the use of electronic systems to facilitate easy registration, including to the extent possible immediate assignment of a registration number.
- Need to permit prompt registration of an unregistered foreign facility, when the failure to register is discovered at the point of import. CRN wishes to emphasize the importance of permitting an unregistered foreign facility to be registered promptly, ideally by electronic means, if a failure to register is noted late in the import process -- at the time prior notice of import is to be submitted, for example.
- Should food categories be required as a part of registration? The Act indicates that FDA may consider whether the registration should include identification of the product category held or handled at each facility, and mentions 21 CFR 170.3

as the appropriate reference in defining food categories. CRN wishes to point out that 170.3 does not include a product category for dietary supplements generally, although it does include a category for “nutrient supplements.” If FDA decides that the food category needs to be indicated, consideration must be given to whether 170.3 is currently adequate to meet the intended use.

- Critical importance of early publication of the final rule. FDA has made it clear that the agency recognizes the need to publish a final rule 60 days or more prior to the December 12, 2003 Congressional deadline for registration of facilities, in order to permit orderly compliance. CRN urges FDA to make every effort to provide the maximum transition time possible, consistent with the agency’s consideration of all the issues that must be resolved.

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. CRN will be pleased to respond to any specific questions FDA may have regarding the dietary supplement industry, to the best of our ability.

Sincerely,



Annette Dickinson  
Vice President, Scientific & Regulatory Affairs