

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 No. 02N-0278, Prior Notice Requirements,
Implementation of Bioterrorism Act of 2002**

The Council for Responsible Nutrition (CRN) is one of the leading trade associations in the dietary supplement industry and submits these comments on the prior notice 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 are extremely concerned about the potential for the prior notice requirements to disrupt commerce to a significant degree. We believe FDA could do a great deal to avert such disruption by streamlining the regulations to the degree permitted by the Act. Specific areas of concern are discussed below.

Multiple notices rather than combined notices

It appears that, if a shipment consists of different kinds of food products, a separate notice must be submitted for each kind of food. FDA also interprets the statutory notice provision for "each article of food" to mean each article of food produced by each manufacturer, therefore requiring **two prior notices** for a single shipment of the same type of food from two different manufacturers. We believe this results in unnecessary duplication of effort both for the agency and for the manufacturers.

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Person Authorized to Submit the Prior Notice

FDA proposes to require that the prior notice be submitted by a purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on behalf of the U.S. purchaser or importer. FDA has proposed to limit the range of those authorized to file a prior notice to:

A purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer. Proposed §1.285.

CRN member companies urge FDA to expand this provision to include licensed customs house brokers.

Additionally, CRN members believe FDA should expand this section to allow an appointed international agent to file the prior notice on the behalf of the importer. Such an agent would be in possession of all necessary information and, therefore, could complete the prior notice as accurately as U.S.-based importers. Adopting this change would in no way negate the fact that the U.S.-based importer remains a responsible party, available for FDA inquiries if the need arises.

The availability of internationally based agents would facilitate the submission of prior notices at times outside of normal U.S. business hours. In this sense, expanding the range of possible filers would alleviate some of the problems raised by the deadlines included in the Proposed Rule.

Time Period for Submission of Prior Notice

According to the proposed rule, prior notice must be submitted to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry. This is unworkable for air cargo shipments, given tight air cargo schedules. It also diminishes the function of ABI/OASIS. Alternative proposal: Use of "Prior notice of distribution", whereby FDA would examine a suspect shipment prior to distribution, would achieve the same end without detaining the goods in the port or other approved location.

For air imports, the contents of the shipment often are not determined nor communicated to the importer until the cargo has departed. These standard operating procedures by carriers make compliance with FDA's Proposed Rule impossible. Another alternative for FDA to consider would be to require notice four hours in advance. This would more accurately reflect the reality of air and truck import.

Even if carriers significantly reorganized normal business operations so that contents of shipments were determined well in advance, FDA's proposed requirement is not practicable. The companies in the dietary supplements business, and in other food industry segments, generally operate on a 5 day/week, 8 hour/day schedule. To ensure that notice was regularly submitted by noon on the prior calendar day, personnel would need to be present seven days a week, 365 days a year in order to ensure that international shipment notices were submitted by the deadline. For small importers, in particular, this requirement would be unduly prohibitive.

Mechanism for Submitting Prior Notice

FDA proposes that the prior notice, and any amendments or updates, must be submitted electronically through FDA's Prior Notice System, a web-based system under development with an anticipated completion date of no later than October 12, 2003. The regulation should allow for prior notice from an automated system.

Need to Permit Updates Regarding Arrival Time

FDA is proposing a two-hour minimum deadline for arrival updates submitted under proposed §1.294. Arrival updates may provide the following information:

1. A change in the port of entry;
2. A delay of more than 3 hours in the anticipated time of arrival;
3. An arrival time of more than 1 hour earlier than anticipated; or
4. Grower identity, if not known when original notice was submitted.

CRN members do not believe the two-hour window is practical for air shipments. Our member companies' experience demonstrates that carriers often do not inform importers of changes in arrival time until the cargo is close to its destination. Given the current state of air and travel security, arrivals frequently do not occur at their scheduled times.

Moreover, the two-hour deadline does not take into consideration that arrival times may change outside of normal business operating hours (i.e. 8 AM to 5 PM). The importer may, therefore, not have access to the altered arrival information within the timeframe required by FDA. In this sense, compliance with FDA's deadline would require importers to run a 24 hour/day operation which simply is not feasible for many operations, especially including small businesses.

CRN urges FDA to modify this requirement so that updates are required by the arrival time. This would allow companies to respond to delayed information coming from carriers and still adequately provide timely information to FDA about when shipments are arriving.

Need to Permit Broader Array of Amendments and Updates

The Proposed Rule permits only a very narrow range of changes to a prior notice, once it is filed. Permitted changes include amendments to product identity information, as described in proposed §1.290, and updates to anticipated arrival information, as outlined in proposed §1.294. If other information provided in the prior notice changes, FDA requires the importer to cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA. Proposed §1.289.

CRN members believe that this limitation is impractical. It is likely that companies filing numerous prior notices will inadvertently make clerical errors in other portions of the highly detailed filing, such as telephone or fax numbers, Customs ACS entry line numbers, or U.S. Customs entry type. It does not make sense to ask importers to reenter three pages of product information in a new prior notice in order to correct what may be simple clerical errors. Such a requirement would be burdensome both to importers and ultimately to the FDA Prior Notice System. CRN therefore urges FDA to be more flexible in its approach to the scope of permissible amendments and updates.

Consequences of Failure to Submit Prior Notice

Under the proposed rule, if a company fails to submit the prior notice, the food will be refused admission under section 801 (m)(1) of the FDCA. If an article of food is refused admission, it must be held at the port of entry unless FDA directs its removal to a secure facility, and cannot be delivered under bond pursuant to section 801 (b) of the FDCA. The person submitting the prior notice or the carrier must arrange for movement of the article of food, under appropriate custodial bond, within the port of entry or to the secure facility and must promptly notify FDA of the location. FDA proposes that transportation and storage expenses be borne by the owner, purchaser, importer, or consignee, but FDA seeks comment on this issue. We propose use of an appeal process.

FDA proposes that the article of food must be held at the port of entry or in the secure facility until prior notice is submitted to FDA in accordance with the rule, FDA has examined the prior notice and determined that it is adequate, and FDA has notified the U.S. Customs Service and the person who submitted the prior notice that the article no longer is subject to refusal of admission under section 801 (m). We oppose this strenuously. Is OASIS the basis for the “may proceed”? We propose: “Unless the FDA executes an “examination” order (OASIS) within 24 hours of the entry date and time, the prior notification requirement will be deemed to have been met.

Changes from Current Practice Regarding Imports

Currently, when an FDA-regulated product is offered for import, brokers submit entry information to U.S. Customs at the border or as part of the official entry. Under current procedures, a food may enter the country at one port and then be transported to another port under a custodial bond before a consumption entry is filed. This may be the case where a container arrives by air but is then trucked to another Customs entry point within

the United States. U.S. Customs then provides entry information to FDA electronically through FDA's Operational and Administrative System for Import Support (OASIS). However, under the current system, the food may have been moving through the country for some time before FDA is made aware of its presence.

The new rules would require notification by noon the day before the food arrives at the port of entry, which is defined for notification purposes as the border crossing or entry point at which the article of food first arrives in the U.S. regardless of the "point of entry" for Customs purposes. Some clarification of the different meanings of "port of entry" for FDA and Customs, is needed. Comment: This is not a workable solution, especially for air cargo shipments, as there is no reference to or consideration of arrival schedules. See alternative proposed above.

Status of Samples for R&D Purposes or Quality Testing

As written, the prior notice requirement outlined in the Proposed Rule is, in our view, overly broad:

prior notice requirements apply to all food that is brought across the U.S. border . . . regardless of whether the food is intended for consumption in the United States. In other words, FDA believes that food that is brought into the United States to be put into foreign trade zones, or for transshipment or reexport immediate or otherwise, is "imported or offered for import" and thus must comply with the prior notice requirements. 68 Fed. Reg. 5430.

The only exemptions FDA contemplated apply to the food that individual travelers carry in their personal baggage for personal use, as well as food subject to the U.S. Department of Agriculture's ("USDA") exclusive jurisdiction under the Federal Meat Inspection Act, Poultry Products Inspection Act or the Egg Products Inspection Act.

While we recognize the importance of tracking the movement of conventional food, dietary supplements and raw ingredients entering the U.S., we urge FDA to add another exemption from the notice requirement for food (i.e., conventional food and dietary supplements), as well as for food ingredients, imported purely for product development (e.g., research and development) or for assessment by quality assurance professionals. Such exempted samples would not be intended for consumption or further distribution.

CRN's member companies frequently receive unsolicited samples of raw ingredients or prototype finished products from vendors hoping to do business with them. In addition, our member companies' overseas personnel have occasion to send the U.S. company samples of raw ingredients and/or finished goods for evaluation or testing. These samples or finished goods generally are not intended for consumption nor are they intended for further distribution. Some of these samples may be shipped to the U.S. quality assurance unit of the company for evaluation in response to foreign consumer complaints or in anticipation of quality assurance testing necessary to respond to inquiries by foreign

regulators. Additionally, foreign finished good manufacturers may send the U.S. company's quality assurance lab retained samples of consumer products in accordance with the company's manufacturing standard operating procedures. It would be unduly burdensome if FDA required the filing of a prior notice in advance of each of shipments of products not intended for consumption and thus not becoming part of the U.S. food supply.

We urge the FDA to exempt R&D/QA samples from the registration and prior notice provision of the Act in the same manner as are products brought in by individuals for personal consumption. In the case of individual importation, the products are for the individual's private use and not for further distribution to others. Similarly, the R&D/QA samples discussed above are brought into the country for specific and limited use, and not for consumption or distribution to any further parties.

Status of Ingredients Not Intended for Food Use

Many of CRN's member companies are also manufacturers of products other than dietary supplements, including pharmaceuticals and cosmetics. Some ingredients can be used in more than one category of products. Various calcium compounds, for example, are widely used in dietary supplements but are also used in some pharmaceutical products or in the manufacture of completely unrelated products such as plastics. CRN urges FDA to make it clear that ingredients being imported for use in non-food products are not subject to the prior notice requirement.

Other Concerns Relating to the Prior Notice Proposal

- Need for seamless integration with existing import requirements. CRN understands that FDA is working closely with other agencies including the Customs Service and USDA in an attempt to coordinate existing requirements with the new FDA prior notice requirements of the Bioterrorism Act of 2002. We wish to underscore the critical importance of ensuring that the new requirements do not create a barrier to trade, in terms of our obligations to trading partners, or create a backlog of shipments at points of entry that would be detrimental to ingredients or products that may be delayed for administrative reasons (as opposed to being held due to safety concerns).
- Need for electronic linkage among import data systems. CRN encourages the agency, as we understand it is already doing, to make every effort to enhance electronic capabilities to permit linkage of the various import notifications required for a food or dietary supplement product or ingredient.
- Need for immediate FDA response to prior notices. CRN joins others in the food industry in emphasizing the need for FDA's acknowledgement of prior notices to be electronic and immediate.
- Need for 24-hour daily operation. In order for the prior notice requirements to be effectively implemented without blocking the flow of trade, CRN agrees with

others in the food industry that it will be essential for FDA port operations to be active 24 hours a day seven days a week.

- Identification of grower, "if known." In the food industry generally, and also in the dietary supplement industry, the grower of a commodity product most often will not be known. The Act requires that the grower be identified as part of the information required in the prior notice, "if known within the specified period of time that notice is required to be provided." CRN urges FDA to provide appropriate flexibility regarding this requirement, to recognize that in many or most cases it will not be feasible to know the grower, and to provide that prior notices that are otherwise acceptable will not be held up solely because the grower's identity is not known.

Thank you for the opportunity to submit 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,



Annette Dickinson
President