



Council for Responsible Nutrition

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July 8, 2003

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

**RE: DOCKET 02N-0275, ADMINISTRATIVE DETENTION
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 about some aspects of FDA's proposed rules on administrative detention of foods, including dietary supplements, when there is credible evidence that the product may present a threat of adverse health consequences.

Need to Distinguish Between Ordinary Recalls and Bioterrorism Threats

The language of FDA's proposal does not appear to distinguish between the type of health concern that would ordinarily trigger a Class I recall and the type of health concern related to potential bioterrorism that would trigger administrative detention. CRN and its member companies do not believe Congress intended for a normal Class I situation to be interpreted as a potential bioterrorism threat that would justify an administrative detention. The rule in its present form raises the concern that any routine inspection could result in a costly detention, rather than the established recall procedures, whenever the inspector believes he or she has credible evidence that an article of food is adulterated or presents a serious threat. CRN believes the intent of the Act is to limit the use of administrative detention to those relatively rare instances where there is reason to suspect potential bioterrorism.

Need for Better Definition of "Credible Evidence"

The Bioterrorism Act and the proposed rule permit a food to be detained during an inspection if an officer or qualified employee of FDA has "credible evidence" that the product presents a threat of serious adverse health consequences or death to humans or animals. Credible evidence is not defined and is apparently to be determined on a case-by-case basis. This does not provide a sufficient safeguard against potentially arbitrary action and does not distinguish between a threat relating to potential bioterrorism and any

other adverse health potential that would normally lead to a Class I recall. We would expect that virtually all actions stemming from normal inspections by FDA personnel would be covered by normal and established recall procedures, with administrative detention under the Bioterrorism Act being invoked only in exceptional and unusual circumstances. To ensure that this is the case, it may be useful to refer to credible evidence suggesting potential bioterrorism. Authorities FDA might rely on for such a determination might include health authorities such as CDC, law enforcement authorities such as the FBI, or other appropriate authorities such as the Department of Homeland Security.

Need to Provide the Company with Fuller Grounds for Detention

CRN and its members are concerned about the potential for arbitrary detention to occur, especially since the detention notice may provide only “a brief, general statement of the reasons for detention.” This will make it difficult for the company to determine the credibility of the evidence or to define the type of information it needs to gather and present if it chooses to appeal the agency’s determination. We believe it is critical that the company be provided with a fuller statement of the grounds for administrative detention.

Conclusion

CRN appreciates the opportunity to comment on FDA’s proposed rule on administrative detention, related to implementation of 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