Docket No. 02N-0275

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE PROPOSED REGULATIONS FOR

ADMINISTRATIVE DETENTION

AS REQUIRED BY

Section 303

of the

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

July 8, 2003

02N-0275

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The American Herbal Products Association ("AHPA") is the national trade association and voice of the herbal products industry, comprised of companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs.

Background

The United States Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act" or "the Act") to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies, and President Bush signed this legislation into law on June 12, 2002. The Act consists of five separate titles. AHPA and its members have significant interest in certain of the statutory requirements established in Title III of the Act (Protecting Safety and Security of Food and Drug Supply) and their implementation.

Joseph Levitt, Director, Center for Food Safety and Applied Nutrition, addressed a letter to the FDA Foods Community dated July 17, 2002. This letter provided, among other things, an overview of those provisions of Title III of the Act that require the Food and Drug Administration (FDA) to issue regulations in an expedited time period. The July 17 letter also solicited comments to identify concerns and to provide recommended solutions and supporting data, if applicable, and requested that initial comments be delivered by August 30, 2002. This request was repeated at a meeting at FDA's College Park, MD offices on July 30, 2002. AHPA provided comments to the FDA following receipt of Mr. Levitt's letter and attendance at FDA's College Park meeting.

On May 9, 2003 (68 Fed. Reg. 25241) FDA published a proposed rule in the Federal Register regarding the Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Subject of these comments

The Comments provided here are in response to the proposed regulations implementing Section 303 of the Act, which authorized, effective immediately upon the enactment of the Act, the detention, on terms defined in the section, of any article of food for which a qualified agent of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. This section also requires that regulations for instituting expedited detentions of perishable foods be promulgated.

Possible impact on AHPA members

Subtitle A of Title III of the Act contains those sections of the Act that are related to protection of the food supply in order to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It is, of course, impossible to speculate on whether a person who would intentionally adulterate a food would choose as their target an herbal dietary supplement, usually consumed in small servings and in a dried form as a tablet or capsule and by a relatively small population, or whether there is a higher likelihood that a more broadly consumed common food with a larger serving size and that is in a form that might be a more viable vector would be identified as a better target. Thus, all AHPA members and all of their products are potentially affected by the administrative detention defined in Section 303.

In addition, while the majority of herbal food products are manufactured using dehydrated plant materials, AHPA's members include persons that manufacturer products that have as ingredients botanicals that are in a non-dehydrated state and so are perishable. Thus, procedures that are provided in the implementing regulations for instituting administrative detention on an expedited basis with respect to perishable foods could have an effect on these companies.

Comments and recommendations

In its preliminary comments to this section of the Act, AHPA noted that there is a possibility that the expanded authority for administrative detention defined in this

section of the Act could be interpreted more broadly than the Congressional intent in providing this authority. In order to protect against such possibility, AHPA suggested that the proposed rule on this subject should define, as nearly as possible without diminishing the usefulness of this authority in protecting the public health by preventing, preparing for and responding to bioterrorism, the level of evidence or information necessary to rise to the level of "credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death in humans or animals." In the preamble to the proposed rule, FDA addressed this issue and determined that no further articulation of this standard was necessary. In so doing, FDA noted that the term "credible evidence" is a term that is addressed in many different contexts in the legal system and that decisions on what constitutes "credible evidence" are necessarily made on a case-by-case basis. Accordingly, FDA has determined not to further define this term in its regulations. AHPA appreciates the discussion and explanation underlying this determination.

In its initial comments, AHPA expressed concern that with regard to herbal ingredients that are perishable, there is some range in the time and conditions that can affect perishability. Some ingredients may be unusable within a very short time, such as a day or less, while others might still be usable after being detained for several days. The conditions under which goods are held, however, will often have a significant influence on the time in which such ingredients can be salvaged. For example, refrigeration or hydration with occasional spraying with water can greatly extend the time in which some ingredient can be maintained in usable condition. AHPA therefore recommended that the development of procedures for instituting administrative detention under this section for perishable foods include some process for requesting from the owners of such foods information as to the best storage methods for assuring the salvage of such foods.

In its proposed regulation, FDA has addressed AHPA's concern in proposed Sec. 1.381(c) which provides that an authorized FDA representative may approve, in writing, a request for a limited conditional release of the detained article of food to maintain or preserve the integrity or quality of the article of food. Thus, FDA has placed the burden on the owner of the detained article to request that special measures be permitted to preserve the integrity or quality of the article of food that is

subject to special preservation conditions. AHPA believes this provision adequately addresses its concern.

Administrative detention is a powerful tool to preserve the integrity of the food supply when it is threatened by adulteration. This tool should be used sparingly and only when the standards set forth in the Act are determined to be present.

Respectfully submitted,

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