CHPA

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August 25, 2006

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

Re: Docket No. 1998N-0359: Request for Comments on the Program Priorities in the Center for Food Safety and Applied Nutrition; 71 *Fed. Reg*. 37083 (June 29, 2006)

Dear Sir or Madam:

The Food and Drug Administration (FDA) requested comments on the program priorities for the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2007 (71 *Fed. Reg*. 37083; June 29, 2006). The Consumer Healthcare Products Association (CHPA) welcomes the opportunity to present its recommendations for CFSAN's top priorities for the upcoming fiscal year and congratulates FDA on its achievements of the previous year. Founded in 1881, CHPA is a national trade association representing manufacturers and distributors of dietary supplements and over-the-counter drug products.

CHPA Dietary Supplements Committee (DSC) members support several of the initiatives that were classified as "A-priorities" in previous years and are listed as FY 2006 Program Priorities. We continue our support of FDA's efforts to fully implement the Dietary Supplement Health and Education Act of 1994 (DSHEA) as it is currently written. Our comments to CFSAN on its program priorities for the upcoming fiscal year focus on regulatory issues related to dietary supplement safety and resource allocation.

Dietary Supplement GMPs

CHPA DSC members strongly encourage publication of the final rule for dietary supplement current Good Manufacturing Practice (GMPs) requirements. We hope the Agency is able to accomplish this goal by December 2006. Our support for releasing the dietary supplement GMPs regulation as soon as possible has been expressed in our previous submissions to FDA (August 9, 2004, and July 18, 2005; Docket No. 1998N-0359). Issuance of the final rule for dietary supplement GMPs will ultimately benefit consumers by establishing manufacturing standards for dietary supplements.

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Proposed Rule for "Gluten-Free" Food Labeling

The Food Allergen Labeling and Consumer Protection Act of 2004 (the Act) requires that a proposed rule to define, and permit the use of, the term "gluten-free" on food labeling be issued no later than two years from date of enactment of the Act (i.e., January 1, 2006). CHPA DSC members extend their support for an expeditious issuance of the proposed rule for "gluten-free" labeling.

Industry Guidance on New Dietary Ingredient Notifications

CFSAN's 2006 Program Priorities list goals related to several guidance documents. CHPA DSC members extend their support for publication of the draft guidance on new dietary ingredient notifications (NDINs) and believe this goal should be a top priority for the Agency. We submitted comments on NDINs on February 1, 2005 (Docket No. 2004N-0454) and welcome the opportunity to review FDA's draft document as soon as possible.

As the NDINs guidance is prepared, CHPA DSC members request the following topics be considered for inclusion in the draft. First, we advocate addressing requirements for safety studies submitted with NDINs in the guidance. We also recommend that, in addition to safety reviews conducted by FDA personnel, the Agency accept the safety findings from an NDIN review conducted by an expert panel, whose qualifications can be verified by FDA. A subsequent review by FDA personnel would not be needed if the Agency accepted the outcome from the expert panel evaluation. Valuable time and Agency resources would not be expended to duplicate this step of the NDIN review process. The number of review cycles necessary for NDIN submissions could also be reduced if the findings from the expert panel were accepted by FDA.

Second, CHPA DSC members would like the NDIN guidance to clarify the types of data that are appropriate for consideration in evaluating the safety of a new dietary ingredient (NDI). Only ingredient information, and not information regarding excipients, should be required to be submitted with NDINs. As all excipients must be either approved food additives or substances generally recognized as safe (GRAS), information on excipients is usually unnecessary for NDINs. Any potential increase in aggregate intake of an excipient should be considered and, if necessary, addressed by the petitioner. Furthermore, DHSEA requires dietary supplement manufacturers to ensure that a dietary supplement is safe, but not that it is efficacious, before it is marketed. Therefore, clinical (i.e., efficacy) data should not be encouraged in NDINs to demonstrate the safety of a new dietary ingredient, except and unless the clinical study was designed to investigate adverse reactions.

Third, CHPA DSC members also recommend that the FDA's guidance document on NDINs stress that safety data should weigh more heavily in the evaluation process than unsubstantiated adverse event claims and/or reports. We believe NDINs should not be delayed or denied due to anecdotal or unverified adverse event reports.

CHPA DSC members applaud the Agency for releasing its final industry guidance entitled "Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 3)" in April 2006. Guidance for NDINs would be equally useful to industry as it works to ensure consumers have access to safe dietary supplement products.

Resource Allocations for CFSAN Activities

CHPA DSC members are sympathetic to the budgetary constraints in which CFSAN currently operates. This economic environment includes losses in full-time equivalent employees (FTEs) and allocated resources. FDA has many responsibilities related to ensuring the safety of the United States food supply, such as its bioterrorism activities and facility inspections. While we recognize the importance of these activities, we hope budget restrictions do not result in diminishing the significance of other ongoing activities of the Agency, such as enforcement on unsubstantiated claims and review of NDINs.

CHPA DSC members thank FDA for this occasion to provide suggestions as the Agency sets its priorities for FY 2007. As opportunities allow, we offer our assistance to FDA as it works to achieve its goals.

Sincerely,

Marcia D. Howard

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Associate Director of Scientific Affairs

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