



Consumer Healthcare
Products Association

July 18, 2005

Food and Drug Administration
Division of Dockets Management (HFA-305)
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; 70 Fed. Reg. 29328-29329 (20 May 2005)

Dear Sir or Madam:

The Food and Drug Administration (FDA) requested comments on establishment of program priorities for the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2006 (70 *Fed. Reg.* 29328-29329; May 20, 2005). The Consumer Healthcare Products Association (CHPA) applauds the FDA for permitting industry to present its recommendations for CFSAN's top goals for FY 2006 and congratulates the Agency on its accomplishments thus far. CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of dietary supplements and over-the-counter drug products.

The CHPA Dietary Supplements Committee (DSC) supports maintaining A-priority level for several goals listed in the 2005 Program Priorities that specifically address dietary supplement issues. We also support FDA's efforts to fully implement the Dietary Supplement Health and Education Act of 1994 (DSHEA) as it is currently written. Our comments reflect recommendations to CFSAN for priorities in the areas of dietary supplement GMPs, dietary supplement claims, and food allergens.

Dietary Supplement GMPs

In November 2004, FDA issued its regulatory strategy for further implementation of DSHEA, in which publication of the final rule for Good Manufacturing Practices (GMPs) was listed as one of the Agency's highest priorities. We agree that publication of the final rule for dietary supplement GMPs should be a top priority for the Agency, having submitted comments to that effect last year (August 9, 2004; Docket No. 1998N-0359). For many years, CHPA members have advocated for issuance of the final rule for dietary supplement GMPs because of their significance to industry, and ultimately to the consumer. We continue to support FDA's

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publication of the rule as soon as possible, as we feel effective GMPs will aid industry in its efforts to provide quality products to the public.

Dietary Supplement Claims

CHPA DSC members support continued A-priority status for many of the goals listed in Part II of the CFSAN 2005 Program Priorities. We especially encourage FDA to publish the draft guidance on the evidence-based ranking system for health claims and qualified health claims (QHCs), replacing the interim guidance released in July 2003, and to issue its proposed rule on regulating QHCs. CHPA commends CFSAN for completing its consumer research on QHC messages, one of the CFSAN 2004 Program Priorities, and our members recommend publication of these data as a top priority for FDA in FY 2006. In publishing these documents, the Agency would be providing additional guidance and information to industry as it explores ways to communicate more effectively with consumers. We extol FDA for issuance of the Dietary Supplement Labeling Guide in April 2005, which further assists industry in its efforts to properly inform the public about its products.

One ongoing priority activity for CFSAN is the development of educational materials providing plain language information on dietary supplements to improve the public's understanding of these products. On July 6, 2004, CHPA members submitted comments under FDA Docket Nos. 1994P-0390 and 1995P-0241 supporting the use of abbreviated health claims that do not contain misleading or untruthful statements and where there is a prominent and immediately adjacent reference directing consumers to additional labeling information satisfying the elements of the model claims language. We recommend FDA give A-level priority (currently B-level priority) to the review of comments submitted on the proposed rule for providing more flexibility in the use of health/nutrient content claims. This will facilitate the goal of developing plain language for enhanced consumer education.

While supporting the majority of the goals regarding dietary supplements, we feel the publication of a proposed rule to amend the description of new dietary ingredients (NDIs) as currently written in 21 CFR 190.6 should *not* be a top priority for the Agency. As stated in comments submitted to FDA on NDIs on February 1, 2005 (Docket No. 2004N-0454), CHPA members oppose any change to the definition of NDIs as currently written in DSHEA. By eliminating this goal, or reducing its priority level, FDA could reallocate manpower and resources towards achieving the Agency's other program priorities.

Food Allergens

CHPA members encourage FDA to maintain A-level priority status for implementation of the Food Allergen Labeling and Consumer Protection Act of 2004 (Act), as noted in the CFSAN 2005 Program Priorities released December 1, 2004. While our members work towards compliance by the January 1, 2006, implementation date, industry welcomes any training and/or

guidance the Agency can provide to assist in this process. For clarification purposes, we recommend that issuance of a guidance document on food allergen labeling requirements established in the Act be included as a top priority for FDA for FY 2006. While labeling requirements are defined in the law, guidance from FDA on ambiguous situations, such as when “may contain” should be used, would be welcomed.

Furthermore, we recommend that development of a comprehensive food allergen strategy addressing areas such as cross-contamination be elevated from its current B-level priority status to A-level status. While creation of a comprehensive strategy is likely to require long-term efforts, it is paramount to ensure the effectiveness of the Act. Scientifically sound methods should be incorporated into any plan developed to apply policies that carry out the spirit of the Act.

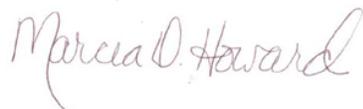
Additional Points of Consideration

CHPA members support the continuation of the ongoing activities listed in the 2005 Program Priorities for dietary supplements and review of health claims for FY 2006. In addition to the joint activities with academia that FDA currently supports for its science-based goals, we encourage FDA to explore opportunities for partnerships with industry and other interested parties, whenever possible, to accomplish the goals outlined for the upcoming fiscal year.

In summary, we recommend that CFSAN establish the release of dietary supplement GMPs as a top priority for FY 2006. Publication of guidance information in the areas of dietary supplement claims and food allergens should also be top priorities for the upcoming year. On the other hand, modification of the definition of NDIs as currently written in DSHEA should *not* be a primary focus of the Agency, and resources dedicated to this project should be redirected to other issues.

CHPA members thank FDA for this occasion to provide suggestions as the Agency sets its priorities for FY 2006. We look forward to opportunities to assist FDA in accomplishing its goals for the upcoming year.

Sincerely,



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Associate Director of Scientific Affairs