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

Re: Docket No. 03N-0069; FDA Task Force on Consumer Health Information for Better Nutrition

Dear Sir or Madam:

On March 13, 2003 FDA announced establishment of an agency Task Force on Consumer Health Information for Better Nutrition. FDA's stated goal is to "encourage the flow of high-quality, science-based information regarding the health benefits of conventional foods and dietary supplements to consumers." The focus of the agency initiative is health claims. The Consumer Healthcare Products Association (CHPA) and the Council for Responsible Nutrition (CRN)[1] support this effort. Representatives of CHPA and CRN participated along with other stakeholders in a March 28, 2003 discussion with FDA officials on this matter.

The Task Force asked for stakeholder views on several issues. One question it posed was whether conventional foods and dietary supplements should be treated the same or treated differently. The purpose of the present comment submitted by CHPA and CRN is solely to address some aspects of this issue.

As the Task Force seeks to identify ways to encourage communication of high-quality, science-based nutrition information to consumers about health claims, it should bear in mind that health information is also conveyed through structure/function claims. Indeed, the average consumer does not know whether a particular claim for a food or

[1] The Consumer Healthcare Products Association is the 122-year old trade association of manufacturers and distributors of over-the-counter drugs and dietary supplements. The Council for Responsible Nutrition is a trade association representing many of the leading ingredient suppliers and product manufacturers in the dietary supplement industry.

dietary supplement is a health claim or a structure/function claim. In 2000, however, FDA took a position that can be expected to create consumer confusion about structure/function claims for conventional foods and dietary supplements with nutritive value. This position is inconsistent with FDA's new policy goal to provide enhanced nutrition information for consumers to help them improve their health.

For at least five years following passage of the Dietary Supplement Health and Education Act, FDA took the position that dietary supplements having nutritive value are also "food," independent of their status as dietary supplements, for purposes of Section 201(g)(1)(C) of the FDC Act. Therefore, structure/function claims for dietary supplements having nutritive value could be made without the disclaimer[2] and notification requirements of Section 403(r)(6) of the Act. For example, FDA agreed that a calcium supplement could make the structure/function claim "calcium builds strong bones and teeth" on the same basis as could a conventional food—without the statutory disclaimer and without notifying FDA. *See* 62 Fed. Reg. 49859 (September 23, 1997).

On January 6, 2000, however, without notice and without an explanation of the need for its action, the agency abruptly reversed itself. In the preamble to the final rule on structure/function claims, FDA declared that claims made for dietary supplements with nutritive value would have to bear the disclaimer, and that the notification and other regulatory requirements would have to be met, or the dietary supplements would be subject to regulation as drugs.[3] FDA said its reversal was based on a re-review of section 201(ff) of the FDC Act.

In February 2000, CHPA and CRN petitioned the agency to reconsider and reinstate its prior position.[4] The petition disagreed with the agency's new interpretation on legal and policy grounds.

From a legal standpoint, the petition cited the plain language of the statute and longstanding legal precedent that a product may be both a dietary supplement and separately a food under the Act. We stated that courts have long held that the definitions

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[2] "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease."

[3] 65 Fed. Reg. 999 at 1033 (January 6, 2000).

[4] The comments submitted today are not intended by CHPA and CRN to supersede any comments or substantive positions taken by the associations in their February 7, 2000 petition, December 22, 2000 comments, or other submissions to Docket 98N-0044. The petition is available at www.fda.gov/OHRMS/DOCKETS/98fr/980044prc2.pdf

under the Act are generally not mutually exclusive and that a product can fall into more than one classification category.[5]

From the policy standpoint of providing good nutrition information to the public, the petition pointed out that consumer confusion and misunderstanding could result from the new FDA interpretation: Consider the label of a conventional food that makes an unqualified structure/function claim that calcium helps builds strong bones, while the identical claim on the label of a dietary supplement bears a disclaimer that "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease." Confronted with the food and supplement products side by side, a consumer could well infer that the calcium tablets' claim is less certain or scientifically based than the claim for calcium in the food. The likelihood of confusion is increased by the fact that FDA has approved a health claim for calcium and osteoporosis,[6] a claim that appears on some dietary supplement products as well as foods without any requirement for a disclaimer. Against this background, use of a disclaimer for the structure/function claim that FDA has not evaluated the calcium claim would be false and misleading since FDA has in fact made such an evaluation.

Similar consumer confusion could result from structure/function claims about the antioxidant properties of vitamins such as C and E, which FDA has acknowledged are derived from their "nutritive value." 59 Fed. Reg. 408 (1994). Under the agency's 2000 position the vitamin claims would have to bear a disclaimer, while conventional food claims would not. In light of the agency's new initiative to enhance consumers' ability to make sound dietary decisions, the FDA's 2000 position raises serious issues of public health policy: In instances where the use of dietary supplements is an important means of assuring adequate intake of many nutrients, the use of the statutory disclaimer would improperly cast doubt on the usefulness of the supplement products.

On October 23, 2000, FDA solicited comment on the CHPA/CRN petition and a second petition filed on the same subject. 65 Fed. Reg. 63256. The agency specifically asked whether consumer confusion would result from a reversion to its prior position since some dietary supplements (i.e., those not based on nutritive value) would still bear

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[5] FDA itself cited *Nutrilab v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983) for this proposition in the preamble to the final rule for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements. 62 Fed. Reg. at 49864. Section 201(ff) expressly provides that dietary supplements are "deemed to be" foods, i.e., are to be treated as food except for purposes of Section 201(g) of the Act, unless, through labeling claims or otherwise, these products are also subject to regulation as drugs. FDA's position that dietary supplements are precluded from being "food" for purposes of Section 201(g)(C) of the Act is thus contrary to the plain language of the Act.

[6] 21 CFR §101.72.

disclaimers while those with nutritive value would not. CHPA and CRN responded that they did not believe that if FDA reinstated its prior position, consumers would be confused by the fact that there would still be some dietary supplement claims with structure/function disclaimers and some without disclaimers. Maintaining absolute consistency for all dietary supplement structure/function claims without regard to the circumstances should not be a policy imperative. The better guide in this situation is to consider what is truthful and meaningful for the consumer. Consumers should receive an accurate and consistent structure/function message that "calcium helps build strong bones" whether the calcium is in orange juice or a dietary supplement.

The FDA position requiring structure/function disclaimers for dietary supplements with nutritive value is directly at odds with the agency's new policy initiative on Consumer Health Information for Better Nutrition. In light of this new initiative, as well as for the reasons set forth in our previous submissions, CHPA and CRN urge the agency to reconsider and reverse the decision to require structure/function disclaimers and notification for dietary supplements with nutritive value.

Thank you for your consideration of our views.

Sincerely,

A Dickinson

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cc: Docket 98N-0044; Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body