DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 31 2003

Bruce Silverglade, Esq.
Director of Legal Affairs
Ilene Ringel Heller, Esq.
Senior Staff Attorney
Center for Science in the Public Interest
1875 Connecticut Avenue, N.W., Suite 300
Washington, D.C. 20009-5728

Re: Docket No. 00P-1227/CP1

Dear Mr. Silverglade and Ms. Heller:

This letter responds to your citizen petition dated March 30, 2000. In that petition, you request that the Food and Drug Administration (FDA) amend the preamble to the final rule on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body (65 FR 1000, January 6, 2000) (Docket No. 98N-0044). You request specifically that FDA prohibit dietary supplements from carrying a structure/function claim if the claim has been approved as a drug claim for over-the-counter (OTC) drugs. If FDA does not enact such a prohibition, you request that structure/function claims on dietary supplements be prefaced by a qualifier ("may," "might," or "may be") if the claim is also an approved OTC indication, or that dietary supplement labels state that the product is not an OTC drug and that FDA has not determined whether the product is safe. For the reasons discussed below, your petition is denied.

I. Request to Prohibit OTC Drug Claims for Dietary Supplements

You argue that dietary supplements should not be permitted to carry the same structure/function claims as OTC drugs because consumers may be misled into believing that dietary supplements and OTC drugs are subject to the same level of regulatory scrutiny.

In the preamble to the final rule on structure/function claims for dietary supplements, FDA responded to comments on the issue of whether dietary supplements may carry the same structure/function claims as an approved OTC drug (65 FR 1000 at 1011). As noted there, one kind of drug claim is a claim related to the effect of the product on the

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structure or function of the body (section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act)) but not related to disease prevention or treatment. In other words, not all drug claims are disease claims.

The authority for dietary supplements to bear structure/function claims comes from section 403(r)(6) of the Act, which specifically excludes claims to "diagnose, mitigate, treat, cure or prevent a specific disease or class of diseases." Thus, dietary supplements may not bear disease claims without prior authorization under the drug or health claim provisions of the Act. However, Congress specifically provided that structure/function claims authorized by section 403(r)(6) of the Act do not, in themselves, subject a dietary supplement to regulation as a drug under section 201(g)(1)(C) of the Act. It thus would not be appropriate to exclude from the scope of acceptable dietary supplement structure/function claims OTC monograph claims or other approved claims for products classified as drugs under section 201(g)(1)(C) of the Act (65 FR 1000 at 1011-12).

II. Request to Require the Use of "May" or a Similar Qualifier

You state that if dietary supplements are permitted to carry structure/function claims that are also drug claims, FDA should require the claim to be prefaced by the words "may," "might," or "may be" when it appears on a dietary supplement.

FDA does not plan to require dietary supplements to use qualifiers if they are otherwise eligible to carry a claim. Based on public input and consumer research, FDA believes that the qualifiers you propose are ineffective. At the Public Meeting on Implementing the Pearson Court Decision and Other Health Claim Issues held on April 4, 2000, FDA asked for input on what the characteristics of appropriate qualifying language would be for dietary supplement health claims.[1] Michelle Rusk of the Federal Trade Commission stated at this meeting that consumer research showed that "simply inserting the word 'may' into the claim . . . had no effect on how consumers viewed the state of the science" (Tr. at 103). She also stated that "consumer evidence on the subject of qualification of claims suggests that it can be very, very difficult to do effective[ly], especially where qualification is necessary to communicate complex scientific information" (Tr. at 101). Three other panel speakers emphasized that qualifying language needs to be strong and direct to be effective (Tr. at 91 ("Disclaimers should be simple, direct, and strongly worded"), 109 ("[Q]ualifying language should be very pointed"), 123 ("[T]here needs to be strong, clear language that qualifies these health claim statements . . .")).

For these reasons, FDA does not believe that use of a qualifier such as "may" would better enable consumers to distinguish between dietary supplements and OTC drugs.

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[1] The transcript for this public meeting is available at http://vm.cfsan.fda.gov/~dms/supplmnt.html, under the Public Meetings heading, Transcript of April 4 meeting: Part One (PDF), Two (PDF) and Three (PDF). The record of the panel that discussed this issue is on pages 89 to 145 of the transcript. These pages are found within Parts One and Two.

III. Request for a Label Statement Informing Consumers That Dietary Supplements Are Not OTC Drugs and Have Not Been Reviewed by FDA for Safety

As an alternative to the use of the word "may" or a similar qualifier for structure/function claims that are also drug claims, you request that FDA require the labels of dietary supplements to state that the products are not OTC drugs and that FDA has not determined whether the products are safe.

FDA is denying your request because of a lack of supporting data. Although the Agency believes it is possible, perhaps even probable, that consumers confuse some dietary supplements with OTC drugs, your petition contains no supporting evidence that consumer confusion exists or that your proposed statement would help to reduce such confusion. We also note that there are some distinguishing features of product labels that may help consumers differentiate between OTC drugs and dietary supplements. For example, dietary supplements bear a distinctive "supplement facts" label and must be identity labeled using the term "dietary supplement" or an appropriate descriptive term that describes the dietary ingredients (e.g., herbal supplement with vitamins). Additionally, dietary supplements marketed with structure/function claims bear a disclaimer prescribed by section 403(r)(6) of the Act that states that the claim has not been evaluated by FDA and that the product is not intended to treat or mitigate any disease. Moreover, under 21 CFR 201.66, all OTC drugs will soon be labeled with uniformly formatted drug facts. Nonetheless, the Agency shares your concern about possible consumer confusion between drugs and dietary supplements and about the ways in which these different product categories are regulated. To that end, we encourage you to submit any data you have that would support your request for additional labeling on dietary supplements.

IV. Conclusion

Although FDA is not granting your petition, the Agency shares your concerns about assisting consumers in accurately evaluating the level of proof behind a claim made on a product. The Agency is evaluating how best to educate consumers while complying with the requirements of the Act. We welcome any suggestions in this regard. In addition, we remain prepared to initiate regulatory action on a case-by-case basis against dietary supplements that violate the Act.

Sincerely yours,

William K. Hubbard
Associate Commissioner
for Policy and Planning