Respondents	No. of respondents	No. of responses/ respondent	Avg. burden per response (in hours)	Total burden (in hours)
Total Burden				169.4

Dated: October 17, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–27118 Filed 10–20–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N 0044]

Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Availability of Citizen Petitions for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of three petitions submitted by Hyman Phelps & McNamara (HP&M), the American Herbal Products Association (AHPA), and jointly by the Council for Responsible Nutrition (CRN) and the Consumer Healthcare Products Association (CHPA). The petitions requested, among other things, that dietary supplements be permitted to make claims about effects on the structure or function of the body that are derived from nutritive value without being subject to the disclaimer and notification requirements of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written comments on the petitions by December 22, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Electronic comments may be submitted via the Internet at www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm or via e-mail: fdadockets@oc.fda.gov. All comments should be identified with the docket number found in brackets in the heading of this document. The petitions are available for review at the Dockets Management Branch (address above) or electronically on the agency's website at http//www.fda.gov/ohrms/dockets/dockets.htm. You may also request copies of the petitions from the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: Rhonda Rhoda Kane, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS 821), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 6, 2000 (65 FR 1000), in the preamble to its final rule entitled ''Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body,'' FDA stated that dietary supplements bearing structure/function claims must comply with the notice, disclaimer, and other requirements of section 403(r)(6) of the act (21 U.S.C. 343(r)(6)). More specifically, the agency stated:

Section 403(r)(6) of the act, by its terms, applies to dietary supplements. The other possible source of authority to make structure/function claims on dietary supplements is section 201(g)(1)(C) of the act, which provides that ''articles (other than food) intended to affect the structure or any function of the body of man or other animals'' are drugs. Under this provision, foods may make claims to affect the structure or function of the body without being regulated as drugs. By its terms, however, section 201(g)(1)(C) of the act exempts a dietary supplement that bears a structure/function claim from drug regulation only if it is also a food. The last sentence of section 201(ff) of the act provides, ''Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.'' The clear import of this language is that dietary supplements are not foods under section 201(g) of the act and therefore cannot qualify for the ''(other than food)'' exception to the drug definition in section 201(g)(1)(C). As a result, dietary supplements that use structure/function claims may do so only under section 403(r)(6) of the act and are therefore subject to the disclaimer, notification, and other requirements in that section and in FDA's implementing regulation. 65 FR 1000 at 1033.

The preamble acknowledged that this conclusion reverses a position stated in the **Federal Register** of September 23, 1997 (62 FR 49859), in the final rule entitled ''Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements.'' The preamble to that rule stated that a dietary supplement could bear a structure/function claim under the ''(other than food)'' exception to the drug definition in section 201(g)(1)(C) of the act (21 U.S.C. 321(g)(1)(C)), provided that the claim was truthful, nonmisleading, and derived from nutritive value (see 62 FR 49859 at 49860, 49863, and 49864). The reversal was based on reconsideration of the plain language of section 201(ff) of the act.

II. The Citizen Petitions

On February 4, 2000, HP&M filed a petition requesting, among other things, that the agency reconsider and revoke its ''pronouncement'' in the January 6, 2000, final rule that all structure/function claims in the labeling of dietary supplements must use the section 403(r)(6) of the act disclaimer and notification procedures. The petition further requests that FDA reinstate its previous position that a structure/function claim in the labeling of a dietary supplement product need not comply with the disclaimer and notification requirements if the claim is truthful, nonmisleading, and derived from nutritive value.

Citing *United States* v. *Ten Cartons * * **Ener-B Vitamin B 12*, 72 F.3d 285, 287 (2d Cir. 1995), HP&M argues that section 201(g)(1)(C) of the act must be applied without reference to section 201(ff) of the act. In sum, HP&M states that the effect of section 201(ff) of the act ''is merely that a dietary supplement will not ''automatically qualify as food.''' HP&M further argues that whether or not a particular dietary supplement qualifies as food is determined by *Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335 (7th Cir. 1983). That case held that a product is a food if it is used primarily for ''taste, aroma or nutritive value.'' *Nutrilab*, 713 F.2d at 338. For example, the petition argues

that calcium would qualify as a food since it is an essential mineral nutrient.

HP&M articulates several other grounds for the action requested in the petition. HP&M also argues that the requirements of section 403(r)(6) of the act apply only to structure/function claims that fall within the health claims definition 21 CFR 101.14(a)(1). Moreover, HP&M argues that FDA's change in interpretation is not entitled to deference because it was issued more than 5 years after the Dietary Supplement Health and Education Act (DSHEA) was passed and, therefore, is not a ''contemporaneous construction'' of the statute. The petition also asserts that Congress intended DSHEA to reduce FDA requirements for dietary supplements. HP&M believes that FDA's new position is inconsistent with congressional intent since it imposes regulatory burdens that did not exist before DSHEA. Finally, the petition also raises an administrative law argument that FDA's reversal is effectively a substantive rule that must comply with the notice and comment rulemaking procedures of the Administrative Procedure Act in 5 U.S.C. 553.

Petitions filed by AHPA and jointly by CRN and CHPA on February 7, 2000, also requested a reversal of FDA's position on this issue. These petitions made arguments similar to those made by the HP&M petition.

III. Questions

The agency is interested in receiving comments on all three petitions. Moreover, there are several specific questions on which FDA would like comment.

1. The outcome of a reversal of FDA's position would be that dietary supplements that qualify for the ''(other than food)'' exception would not have to accompany the structure/function claim with a disclaimer while dietary supplements that do not qualify would. Would consumer confusion result from this outcome?

2. The outcome of maintaining the current position would be that dietary supplements making a structure/function claim would have to bear a disclaimer while conventional foods making the same claim would not. Is it better to have an inconsistency between dietary supplements and conventional foods or between dietary supplements that qualify for the ''(other than food)'' exception and dietary supplements that do not?

3. If FDA were to reverse its position as requested by the petitions, the agency would be notified of some structure/function claims for dietary supplements, but not others. Therefore, the agency would not be aware of all the structure/function claims in the marketplace, including some that might be in fact disease claims rather than legitimate structure/function claims. To determine whether a dietary supplement could legitimately bear a structure/function claim without a disclaimer, FDA would have to investigate whether the claim was based on the nutritive value of the supplement. What would be the impact of this situation on enforcement?

IV. Comments

You may submit to the Dockets Management Branch (address above) written or electronic comments by December 22, 2000. Electronic comments may be submitted via the Internet to: www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm or via e-mail: fdadockets@oc.fda.gov. Groups or organizations must submit two copies of any comments. Individuals may submit one copy of their comments. Identify your written comments by placing the docket number at the top of your comment(s). If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Any comments submitted will be filed under the docket number identified in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 13, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–27083 Filed 10–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Panel: To provide advice and recommendations to the agency on scientific disputes between the Center for Devices and Radiological Health and sponsors, applicants, and manufacturers.

Date and Time: The meeting will be held on October 31, 2000, 1 p.m. to 4 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Les S. Weinstein, Center for Devices and Radiological Health (HFZ–5), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, e-mail: lsw@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10232. Please call the Information Line for up-to-date information on this meeting.

Agenda: The members of the newly established Medical Devices Dispute Resolution Panel will be introduced to the public and will hear presentations by FDA staff on the purpose of the panel and its role in dispute resolution.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues regarding resolving scientific disputes concerning medical devices and on the role of this panel. Written submissions may be made to the contact person by October 25, 2000. Oral presentations from the public will be scheduled between approximately 2 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the October 31, 2000, Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).