

and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Copies of these guidance documents also are available on the Internet at <http://www.cfsan.fda.gov/dms/guidance.html>. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

Dated: January 3, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-542 Filed 1-4-02; 4:12 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-0044]

#### Small Entity Compliance Guide: "Structure/Function Claims;" Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in the **Federal Register** of January 6, 2000 (65 FR 1000), entitled "Regulations on Statements Made for Dietary Supplements Concerning the Effect on the Structure or Function of the Body." This SECG is intended to set forth the requirements of that final rule in plain language and to help small businesses understand the regulation.

**DATES:** Submit written or electronic comments on the SECG at any time.

**ADDRESSES:** Submit written comments concerning this SECG to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the SECG to the Industry Activities Staff (HFS-565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

**FOR FURTHER INFORMATION CONTACT:** Robert Moore, Center for Food Safety and Applied Nutrition (HFS-811), Food

and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4605, FAX 202-205-4594.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 6, 2000 (65 FR 1000), FDA issued a final rule defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. The regulation also established criteria for determining when a statement about a dietary supplement is a claim to diagnose, cure, mitigate, treat, or prevent disease. The final rule clarified the types of claims that may be made for dietary supplements without prior review by FDA and the types of claims that require prior authorization as health claims or prior approval as drug claims. This final rule became effective February 7, 2000.

FDA examined the economic implications of that final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-602). The agency determined that the final rule would have a significant economic impact on a substantial number of small entities.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), FDA is making available this SECG stating in plain language the requirements of this regulation.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### I. Comments

Interested persons may, at any time, submit written or electronic comments on the SECG entitled "Structure/Function Claims; Small Entity Compliance Guide" to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the SECG and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### II. Electronic Access

Copies of the SECG may also be viewed on a personal computer with access to the Internet. The Center for

Food Safety and Applied Nutrition's home page includes the SECG, which can be found at <http://www.cfsan.fda.gov/dms/guidance.html>.

Dated: December 26, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-451 Filed 1-8-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Advisory Council.

*Date:* February 7-8, 2002.

*Open:* February 7, 2002, 8:30 a.m. to 2 p.m.

*Agenda:* For discussion of program policies and issues.

*Place:* National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, MD 20892.

*Closed:* February 7, 2002, 2 p.m. to Adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Deborah P. Beebe, PhD, Director, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Two Rockledge Center, Room 7100, 6701 Rockledge Drive,