DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0583]

Food Security Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidance documents related to food security entitled ''Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance'' and ''Importers and Filers: Food Security Preventive Measures Guidance.'' ''Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance'' is designed as an aid to operators of food establishments (i.e., firms that produce, process, store, repack, relabel, distribute, or transport food or food ingredients, or that prepare or distribute food at retail). It identifies the kinds of preventive measures that they can take to minimize the risk that food under their control will be subject to tampering or criminal or terrorist actions. ''Importers and Filers: Food Security Preventive Measures Guidance'' is designed as an aid to operators of food importing establishments, storage warehouses, and filers. It identifies the kinds of preventive measures that they can take to minimize the risk that food under their control will be subject to tampering or criminal or terrorist actions.

DATES: Submit written or electronic comments by March 11, 2002 to ensure their adequate consideration in the preparation of revised guidance, if warranted. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance'' or ''Importers and Filers: Food Security Preventive Measures Guidance'' to John Kvenberg, Office of Field Programs (HFS–600), Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the guidance documents to Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: John Kvenberg, Office of Field Programs (HFS–600), CFSAN, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–205–4187, e-mail:jkvenberg@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Operators of food establishments, food importing establishments, and filers are encouraged to review their current procedures and controls in light of the potential for tampering or criminal or terrorist actions and make appropriate improvements. ''Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance'' aids operators of food establishments (i.e., firms that produce, process, store, repack, relabel, distribute, or transport food or food ingredients, or that prepare or distribute food at retail). It is relevant to all sectors of the food system (i.e., from farm-to-table), including farms, aquaculture facilities, fishing vessels, producers, transportation operations, processing facilities, packing facilities, warehouses, retail, and food-service establishments. ''Importers and Filers: Food Security Preventive Measures Guidance'' aids operators of food importing establishments, storage warehouses, and filers. Both guidance documents identify the kinds of preventive measures that operators can take to minimize the risk that food under their control will be subject to tampering or to criminal or terrorist actions. They take the operator through each segment of the farm-to-table system that is within their control, in order to minimize the risk of tampering or of criminal or terrorist action at each segment. Implementation of these measures requires commitment from both management and employees to be successful and, therefore, both should participate in their development and review.

The two guidance documents are level 1 guidances issued consistent with FDA's good guidance practices regulation (GGPs) (21 CFR 10.115). The agency is soliciting public comment, but is implementing these two guidance documents immediately in accordance with § 10.115(g)(2) (21 CFR 10.115(g)(2)). The two guidance documents were prompted by the tragedies of September 11, 2001, and the resulting scrutiny of, and interest in, food safety and security that followed. FDA believes it is critical to our national interest and the public health to make guidance on food security available to the food industry quickly. Thus, the agency has determined that prior public participation is not feasible or appropriate.

FDA is also interested in comments on whether the guidance documents ''Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance'' and ''Importers and Filers: Food Security Preventive Measures Guidance'' should be revised to include the following additional preventive measures:

- The use of tamper-evident packaging. FDA is particularly interested in information on: the utility of the various methods of tamper-evident packaging in minimizing the risk that foods so packaged will be subject to tampering or criminal or terrorist actions; and, the practicality of applying tamper-evident packaging to the broad spectrum of foods presently in commerce;
- The use of procedures and/or records that enable shipments of food from a food establishment or food importing establishment to be traced to shipments of food received by the food establishment or food importing establishment and vise versa. FDA is particularly interested in information on the types of procedures and/or records that are both practical and effective in facilitating trace-back of incoming shipments, trace-forward of outgoing shipments, and linkages between the two.

These guidance documents represent the agency's current thinking on appropriate measures that can be taken by operators of food establishments, food importing establishments, storage warehouses, and filers to minimize the risk of food being subjected to tampering or criminal or terrorist actions. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the guidance documents at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance documents

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]

BILLING CODE 4160–01–S

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]

BILLING CODE 4160–01–S

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,