there plans to regularly evaluate progress toward the stated objective(s)? Is an appropriate work plan included?

Has the applicant met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

3. Innovation: Does the project employ novel concepts, approaches, or methods? Are its aims innovative? Does it challenge existing paradigms? Will it test the efficacy of new methodologies or technologies?

4. Investigator(s): Is the principal investigator an experienced researcher? Have any of the investigators conducted research in the area of proposed study?

5. Environment: Will the proposed research setting contribute to the probability of success? Does the proposed study take advantage of any unique features of research setting? Are there any collaborative agreements? Is there evidence of institutional/organizational support? Is there evidence of appropriate interest, commitment, and cooperation among the investigators and other interested parties as evidenced by letters detailing the nature and extent of involvement?

6. Human Subjects: Does the application adequately address the requirements of 45 CFR Part 46 for the protection of human subjects?

7. Biohazards: Are any hazards procedures proposed which would affect the safety and well-being of the research subjects and/or investigators?

8. Budget: Does the proposed budget seem appropriate? Does the proposed study length seem reasonable? Would you propose any modifications?

The secondary review committee, in the course of its review, will consider the following factors:

a. The results of the peer review (SEP).

b. The significance of the proposed activities in relation to the priorities and objectives stated in Healthy People 2000 and this program announcement.

c. National needs.

d. Program balance including currently funded research and organizational considerations.

e. Budgetary considerations.

H. Other Requirements

Technical Reporting Requirements Provide CDC with original plus two copies of:

1. An annual progress report;

2. A financial status report, no more than 90 days after the end of the budget period; and

3. A final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to: Sharron Orum, Grants Management Specialist, Procurement and Grants Office, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 2920 Brandywine, Room 3000, Atlanta, GA 30341.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application package.

AR–1	Human Subjects Requirements.
AR–2	Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
AR–8	Public Health System Reporting Requirements.
AR–9	Paperwork Reduction Act Requirements.
AR–10	Smoke-Free Workplace Requirements.
AR–11	Healthy People 2000.
AR–12	Lobbying Restrictions.

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act [42 U.S.C. sections 301 and 317(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where to Obtain Additional Information

Please refer to Program Announcement Number 99108 when requesting information. To receive additional written information and to request an application kit, call 1–888-GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine, Room 3000, Atlanta, GA 30341, Telephone: (770) 488–2716, Email address: spo2@cdc.gov.

See also the CDC home page on the Internet: http://www.cdc.gov.

For program technical assistance, contact: Betsy L. Thompson, Centers for Disease Control and Prevention (CDC), Epidemiology Program Office, Div. of Prevention Research and Analytic Methods, Rm 1050B, 1600 Clifton Road, M/S D01, Atlanta, GA 30333, Telephone: (404) 639–3806, Email address: bst0@cdc.gov.

Dated: April 5, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–8848 Filed 4–8–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0391]

International Standard-Setting Activities; Codex Alimentarius Commission; Committee on Nutrition and Foods for Special Dietary Uses; Background Paper to Identify Perspectives and Issues Pertaining to International Guidelines on Vitamin and Mineral Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is asking interested persons to submit comments that will be used by the U.S. delegate to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to prepare a background paper to be considered by the CCNFSDU prior to its considering the appropriateness of establishing guidelines for vitamin and mineral supplements for the purposes of international trade. The background paper will discuss the range of concerns and the differences in rationales on this topic. The United States, which has indicated its opposition to the development of such guidelines, has been asked to participate in the development of this background paper along with other governments. FDA is accepting this request in its role as the agency representing the United States in the CCNFSDU.

DATES: Submit written comments by June 8, 1999.

ADDRESSES: Submit written comments and recommendations to the Dockets Management Branch (HFA–305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4605.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Codex Alimentarius Commission (Codex) is the joint food standards program of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). This program was established in 1962 and develops food standards, codes of practice, and other guidelines to help protect the health and economic interests of consumers and to facilitate and encourage fair international trade in food. The Codex accomplishes these actions through the use of subordinate committees that develop food standards, codes of practice, and other guidelines for consideration and adoption by the Codex and member countries.

In the United States, the U.S. Department of Agriculture (USDA), FDA, and other agencies manage and carry out U.S. Codex activities. Executive direction of this effort comes from the U.S. manager for Codex, a responsibility of the Food Safety and Inspection Service (FSIS) of USDA. For more information on U.S. Codex activities and the responsibilities of the U.S. delegates to Codex committees, see the **Federal Registers** of May 27, 1998 (63 FR 28966), and February 12, 1998 (63 FR 7118), respectively. Under section 491 of the Trade Agreements Act of 1979 (19 U.S.C. 2578), as amended, and the Uruguay Round Agreements Act, Pub. L. 103–465, 108 Stat. 4809, FSIS must inform the public of the sanitary and phytosanitary standard setting activities of international standard-setting organizations, such as Codex. The most recent annual notice was published in the May 27, 1998, **Federal Register**. That notice identified FDA as the responsible agency for the United States with respect to the activities of the CCNFSDU (63 FR 28966 at 28973). Accordingly, the U.S. delegate to the CCNFSDU is from FDA.

This notice solicits information and comments relative to the content of a background document that is intended to identify the nature of and basis for differences in perspectives on establishing guidelines for vitamin and mineral supplements in international trade. This document is a component of the sanitary and phytosanitary standard-setting activities of the CCNFSDU with regard to its consideration of guidelines for vitamin and mineral supplements (Ref. 1).

II. Background

Germany proposed a process to consider the development of guidelines for vitamin and mineral supplements at the October 1995 meeting of the CCNFSDU. Germany submitted the draft proposed guidelines (Ref. 2), which were intended to address such issues as the composition and labeling of vitamin and mineral supplements, including lists of allowable vitamins and minerals and their sources, minimum and maximum levels, permissible additives, packaging, labeling requirements, and permissible claims. Codex circulated the proposal to member governments for comment, and it was considered at the October 7 to 11, 1996, CCNFSDU committee meeting (Ref. 3).

At that meeting, the United States, through its delegate, indicated its opposition to the development of the guidelines. Such guidelines would not affect dietary supplements within the United States, whose sale and marketing is regulated under the Federal Food, Drug, and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act of 1994. However, such guidelines, were they developed and adopted by other countries, could affect international trade in vitamin and mineral supplements. In particular, such guidelines could have ramifications for those U.S. manufacturers of dietary supplements that export their products to countries that adopt such guidelines.

CCNFSDU did not reach consensus on many aspects of the draft proposed guidelines, but nonetheless, they forwarded the draft proposed guidelines to Codex and recommended that the draft proposed guidelines be advanced to the next level of consideration. Codex considered the recommendation of the committee at its June 23 to 28, 1998, meeting in Rome, Italy (Ref. 4). The United States, through its delegate, again indicated its opposition to the advancement of the guidelines during the Codex meeting.

Codex did not advance the draft proposed guidelines to the next level of consideration, but instead Codex returned them to the CCNFSDU for further discussion and consideration. Codex also advised the CCNFSDU to reconsider whether there was a need to proceed with the development of the guidelines.

The CCNFSDU considered the draft proposed guidelines again at its September 21 to 25, 1998, meeting (Ref. 1). A copy of this document may be downloaded from the internet at ''www.fao.org/es%2A/esn/codex/reports.htm''. The CCNFSDU discussed the draft proposed guidelines and decided that while it was premature to stop work on the draft proposed guidelines, there was not enough agreement to advance the proposed draft guidelines for vitamin and mineral supplements to the next level of consideration. Consequently, the draft proposed guidelines remained at their current level of consideration. Because there was no consensus on the need for the proposed guidelines or what they should contain, the CCNFSDU decided that it would be useful to reconsider the basis for continuing work on the draft proposed guidelines. The CCNFSDU believed that it would facilitate its work if it could prepare a background paper that would: (1) Provide ''a neutral and objective presentation on the issues that should be considered on this subject'', (2) ''help understand the rationale behind the different approaches'', and (3) ''be useful to study in depth the principles justifying each particular position in order to find a common ground for discussion'' (Ref. 1).

The CCNFSDU chair asked the U.S. Government to contribute to this background paper, which will be considered at the next meeting of the CCNFSDU in the year 2000. The U.S. delegate agreed to this request. The U.S. delegate concluded that there is value in assisting with the development of an objective background paper that addresses the various perspectives, approaches, and difficulties associated with developing guidelines for international trade in vitamin and mineral supplements. This activity is consistent with the U.S. interests in this matter and will facilitate the decisionmaking process of the CCNFSDU.

III. Request for Comments

Interested persons may, on or before June 8, 1999, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments regarding this proposal. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Based on the interest of the CCNFSDU in identifying the pros and cons of developing guidelines for vitamin and mineral supplements and in identifying

the various factors and principles pertaining to international guidelines for vitamin and mineral supplements, FDA is asking for comments that identify the range of perspectives associated with the manufacture, use, and regulation of such products, as well as the specific issues that the paper should address. Moreover, the CCNFSDU intends to develop a paper that considers only issues relevant to vitamin and mineral supplements. The CCNFSDU does not intend that the paper will consider the addition of vitamins and minerals to conventional foods nor products containing other ingredients or substances, for example herbs or other botanicals. Accordingly, comments on such matters will not assist the U.S. delegate to contribute to the CCNFSDU paper.

For the purposes of international trade, FDA has identified topics that should be addressed in the background paper. The topics identified for comment are as follows: (1) Topic 1 focuses on terminology, such as the use of the terms ''food supplements'' or ''dietary supplements,'' as compared to ''vitamin and mineral supplements;'' (2) topic 2 focuses on the purpose and role of vitamin and mineral supplements; (3) topic 3 focuses on the concept of ''approved nutrients'' (i.e., a positive or negative list of nutrients for use in the supplements of issue); (4) topic 4 focuses on setting maximum levels for vitamins and minerals in supplement form; (5) topic 5 focuses on setting minimal limits for vitamins and minerals in such products; (6) topic 6 focuses on purity and good manufacturing practices; (7) topic 7 focuses on labeling, warning statements, and claims; and (8) topic 8 focuses on packaging and marketing.

For each topic, specific comments would be most helpful if they addressed the following: (1) Is there a need for the topic? (2) What are the various perspectives on the topic and what the difficulties in addressing these perspectives? and (3) What are the options for making decisions about the topic?

We also welcome comments on the inclusion of additional topics. It would be most helpful if the additional topic(s) could be addressed in a fashion so as to respond to the three basic questions identified for the other topics listed previously.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Codex Alimentarius Commission, ''Report of the Twenty-First Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses,'' ALINORM 99/26, FAO/WHO, Rome, 1998.

2. Codex Alimentarius Commission, ''Report of the Twentieth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses,'' ALINORM 97/26, FAO/WHO, Rome, 1996.

3. Codex Alimentarius Commission, ''Report of the Nineteenth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses,'' ALINORM 95/26, FAO/WHO, Rome, 1995.

4. Codex Alimentarius Commission, ''Report of the Twenty-Second Session of the Codex Alimentarius Commission,'' ALINORM 97/4, FAO/WHO, Rome, 1997.

Dated: April 2, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8796 Filed 4–8–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Advisory Board to the National Center for Toxicological Research; 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Advisory Board to the National Center for Toxicological Research (NCTR).

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 26, 1999, 12 noon to 5:30 p.m., and April 27, 1999, 8:30 a.m. to 1 p.m.

Location: NCTR, Bldg. #12, Conference Center, Jefferson, AR.

Contact Person: Ronald F. Coene, NCTR (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12559. Please call the Information Line for up-to-date information on this meeting.

Agenda: The board will be presented with draft reports on evaluations of three of NCTR's programs in Biochemical Toxicology, Genetic Toxicology, and Molecular Epidemiology, for their review, discussion, and approval. The draft reports are the products of three site visit teams who conducted on-site reviews over the last year. The staff from these programs will provide a preliminary response to the issues raised and recommendations made. Two progress reports will be presented to the board on the recommendations it made at its last meeting on NCTR's Neurotoxicology Program and Biometry and Risk Assessment Program. The NCTR Director will also provide a center update.

Procedure: On April 26, 1999, from 12 noon to 5:30 p.m., and April 27, 1999, from 8:30 a.m. to 12 noon, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Written submissions may be made to the contact person by April 15, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on April 27, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 15, 1999, 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.

Closed Committee Deliberations: On April 27, 1999, from 12 noon to 1 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

The Commissioner approves the scheduling of meetings at locations outside the Washington, DC area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

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

Dated: April 1, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–8938 Filed 4–8–99; 8:45 am]

BILLING CODE 4160–01–F