

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.*

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## 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.*

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