

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99 N-1 174]

Dietary Supplements; Center for Food Safety and Applied Nutrition Strategy; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

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SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit comments that will assist the Center for Food Safety and Applied Nutrition (CFSAN) to develop an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act (DSHEA). This meeting is intended to give the public an opportunity to comment on the development of the strategy.

DATE: The meeting will be held on June 8, 1999, from 10 a.m. to 4 p.m. Submit written comments by May 28, 1999.

ADDRESSES: The meeting will be held at the Cohen Bldg., auditorium, 330 Independence Ave. SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Naomi Kulakow, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW. Washington, DC 20204, 202-205-8682, FAX 202-260-8957, e-mail nkulakow@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

This meeting is the first of two meetings to seek stakeholder comments on the development of an overall strategy for achieving effective regulation of dietary supplements under the Federal

Food, Drug, and Cosmetic Act, as amended by DSHEA. The meetings will build upon themes that emerged from a broader stakeholder meeting sponsored by CFSAN in June 1998. That meeting addressed the nonfood safety initiative programs that are managed by CFSAN and identified some basic themes including: (1) The need to maintain a credible FDA program, including compliance, enforcement, and consumer outreach activities that will help ensure consumer confidence in FDA regulated products; (2) the need to maintain a solid, science based program staffed with highly qualified scientists; and (3) the recognition that FDA's assistance to consumers and the regulated industry is important.

II. Registration and Requests for Oral Presentations

If you would like to attend the meeting, you must register with the contact person (address above) by May 28, 1999, by providing your: Name, title, business affiliation, address, telephone, and fax number. To expedite processing, registration information may also be faxed to 202-260-8957. If you need special accommodations due to disability, please inform the contact person when you register.

If you wish to make an oral presentation during the meeting, you must inform the contact person of that desire when you register to attend and submit: (1) A brief written statement of the general nature of the evidence or arguments that you wish to present, (2) the names and addresses of the persons who will give the presentation, and (3) the approximate length of time that you are requesting for your presentation. Depending on the number of people who register to make presentations, we may have to limit the time allotted for each presentation.

III. CFSAN'S 1999 Program Priorities Document

The meeting announced in this notice, as well as a meeting to be announced later on the west coast, are in response to CFSAN's 1999 Program Priorities document that calls for the development of an overall dietary supplement strategy in conjunction with other agency units and

stakeholders. A copy of the priorities document is available on the Internet on FDA's Website at '<http://vm.cfsan.fda.gov/~dms/cfsan199.html>'.

The priorities document states that the overall strategy should address all elements of the dietary supplement program including: (1) Boundaries between dietary supplements and conventional foods, between dietary supplements and drugs, and between dietary supplements and cosmetic products; (2) claims; (3) good manufacturing practices; (4) adverse event reporting; (5) laboratory capability; (6) research needs; (7) enforcement; and (8) resource needs. FDA's objective in developing this strategy is to ensure consumer access to safe dietary supplements that are truthfully and not misleadingly labeled. FDA intends to develop this strategy by following a process of openness, flexibility, efficiency, and commitment to public health.

FDA has identified four criteria for priority ranking the tasks encompassed in the strategy. These criteria are: (1) Enhancement of consumer safety, (2) development of health-related product labeling regulation, (3) improvement in efficiency of operation, and (4) closure on unresolved regulatory issues.

This meeting also addresses activity undertaken by the agency to solicit comments in accordance with section 406(b) of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-1 15) (21 U.S.C. 393(b)).

IV. Agenda and Goals

To help focus comments for the June 8, 1999, meeting, FDA requests that oral and written input regarding an overall strategy for achieving effective regulation of dietary supplements address the following questions:

1. In addition to ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy should include?
2. Are the criteria for prioritizing the tasks within the supplement strategy appropriate? Which specific tasks should FDA undertake first?

3. What factors should FDA consider in determining how best to implement a task (i.e., use of regulations, guidance, etc.)?

4. What tasks should be included under the various dietary supplement program elements in the CFSAN 1999 Program Priorities document?

5. Are there current safety, labeling, or other marketplace issues that FDA should address quickly through enforcement actions to ensure, for example, that consumers have confidence that the products on the market are safe and truthfully and not misleadingly labeled?

6. Toward what type or area of research on dietary supplements should FDA allocate its research resources ?

7. Given FDA's limited resources, what mechanisms are available, or should be developed, to leverage FDA's resources to meet effectively the objective of the strategy?

V. Comments

Interested persons may, on or before May 28, 1999, submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may also send comments to the Dockets Management Branch via e-mail to "FDA Dockets @bangate.fda.gov" or via the FDA Website "http://www.fda.gov". You should annotate and organize your comments to identify the specific issues to which they refer. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

You may request transcripts of the meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. You may also

examine the transcript of the meeting at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Website "http://www.fda.gov".

Dated: 5/6/99
May 6, 1999

William K. Hubbard

William K. Hubbard
Acting Deputy Commissioner for Policy

[FR Dec. 99-???? Filed ??-??-99; 8:45 am]

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Crystal Williams Day