

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 96N-0417]

Dietary Supplements; Current Good Manufacturing Practice Regulations; Public Meetings

AGENCY: Food and Drug Administration, HHS

ACTION: Notification of public meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing two public meetings to discuss the proposed rule entitled "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements" that published in the **Federal Register** of March 13, 2003 (68 FR 12157). These meetings are intended to provide clarification of the proposed rule and to explain how to submit comments on the proposed rule. These meetings will provide stakeholders and interested parties, including small businesses, an opportunity to ask questions about the proposed rule.

DATES: The public meetings will be held on the East coast on Wednesday, April 29, 2003, from 9 a.m. to 12 noon and 1:30 p.m. to 5 p.m. and on the West coast on Monday, May 6, 2003, from 9 a.m. to 12 noon and 1:30 p.m. to 5 p.m. For security and space limitation reasons, you are encouraged to register early. You may preregister via the Internet and fax until close-of-business 2 business days before the meeting and onsite on the day of the meeting, provided that space is available.

ADDRESSES: *East coast meeting:* The first public meeting will be held at the Center for Food Safety and Applied Nutrition, Harvey W. Wiley Auditorium, 5100 Paint Branch Pkwy., College Park, MD 20740.

West coast meeting: The second public meeting will be held at the

Ronald V. Dellums Federal Bldg., 3d floor auditorium, North Tower, 1301 Clay St., Oakland, CA 94612-5213.

A written transcript of the meeting and submitted comments will be available for viewing at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the FDA Web site (see **III. Electronic Access**).

FOR FURTHER INFORMATION CONTACT:

For the East coast meeting: Kenneth Taylor, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1439, FAX: 301-436-2639, or e-mail: Kenneth.Taylor@cfsan.fda.gov.

For the West coast meeting: Janet McDonald, FDA/San Francisco District, 1431 Harbor Bay Pkwy., Alameda, CA 94502-7070, 510-337-6845, FAX: 510-337-6708, or e-mail: Janet.McDonald@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1994, the Dietary Supplement Health and Education Act (DSHEA) amended the Federal Food, Drug, and Cosmetic Act. DSHEA, among other things, provided FDA with express statutory authority to prescribe current good manufacturing practices (CGMPs) for dietary supplements (21 U.S.C. 342(g)). In the **Federal Register** of March 13, 2003 (68 FR 12157), FDA published a proposed rule entitled "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements" to establish CGMPs that include provisions on manufacturing, packaging, labeling, testing, quality control, releasing for distribution, and holding of dietary ingredients and dietary supplements. The proposed CGMPs are intended to ensure that manufacturing practices will not result in an adulterated dietary supplement and that dietary supplements are accurately labeled.

These public meetings will provide an opportunity to brief stakeholders on the proposed rule and allow them to ask questions about the proposed rule. They are also intended to fulfill part of the outreach requirement of the Small Business Regulatory Enforcement Fairness Act of 1996.

Agenda: The daylong meetings will have two sessions: The morning session will target interested parties including both small and large firms that manufacture, package, or hold dietary ingredients and dietary supplements; and the afternoon session will target small firms. Small firms are encouraged to attend both sessions.

The morning agenda will include an overview of the proposed rule and the following specific topics: (1) Personnel, (2) physical plant, (3) equipment and utensils, (4) production and process controls, (5) holding and distributing, (6) consumer complaints, and (7) recordkeeping. In addition to explaining the content of the proposed rule, we will instruct participants on the process for submitting comments. We will also discuss the types of information that we are interested in obtaining, i.e., information that would be relevant to developing a final rule and to the economic impact of the rule. Lastly, we will describe how the Small Business Administration can help small firms that might be affected by the proposed rule.

The afternoon session will provide small businesses an opportunity to ask questions about the proposed rule. They can ask about any special implications to small businesses and about any items from the morning presentations that need more clarification. We will provide information on the process for submitting comments and on the types of information that we are interested in obtaining from small businesses, i.e., information that would be relevant to developing a final rule and to the economic impact of the rule. The session will begin with a short presentation on the Federal rulemaking process, including how to effectively comment on rules in general and how to address particular questions that the Government has requested comment on. Following the presentation, participants will be asked to break into smaller groups to facilitate open discussion.

Comments: To submit written comments on the proposed rule, please follow the instructions in the "Request for Comments" section of that document (68 FR 12157, March 13, 2003).

II. Registration

You may preregister for either meeting via the Internet (see **III. Electronic Access**) or by fax (see **FOR FURTHER INFORMATION CONTACT**) until