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

close-of-business April 24, 2003, for the East coast meeting and May 1, 2003, for the West coast meeting, or you may register onsite on the day of the meeting. Registrations will be accepted on a space-available basis. If you need special accommodations due to a disability, please inform the contact person at least 7 days in advance (see **FOR FURTHER INFORMATION CONTACT**).

There is no registration fee for these public meetings, but early registration is encouraged because space is limited and it will expedite entry into the building and parking area. Because the meeting will be held in a Federal building, you should also bring a photo ID and plan for adequate time to pass through security screening systems. For the West coast meeting, please be aware that the building management enforces the rule that no food or drink, including water, is allowed in the auditorium.

Registration Form Instructions: You may register for either meeting via the Internet (see **III. Electronic Access**). You may also register by faxing the following registration form to the contact person for the meeting that you plan to attend (see **FOR FURTHER INFORMATION CONTACT**).

REGISTRATION FORM
PUBLIC MEETING TO DISCUSS THE PROPOSED RULE TO ESTABLISH CGMP REGULATIONS

Name:

Title:

Company:

Address:

Telephone:

Fax:

E-mail:

Please indicate the type of organization that you represent.

___ Industry
___ Government
___ Consumer Organization
___ Media
___ Healthcare Professional
___ Law Firm
___ Education Organization
___ Other (specify) _____

III. Electronic Access

You may register for either meeting or obtain updates to this announcement and additional related information on the Dietary Supplements home page at *http://www.cfsan.fda.gov/~dms/supplmnt.html*, scroll down the page to ''Recent Announcements.'' Transcripts of the public meetings and submitted comments will be available at *http://www.cfsan.fda.gov/~dms/ds-ind.html* under ''Good Manufacturing Practices (GMPS).''

IV. Transcripts

You may request a transcript of the public meeting 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. The transcript of the public meetings and submitted comments will be available for public examination at the Dockets Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Web site (see **III. Electronic Access**).

Dated: March 24, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–7377 Filed 3–27–03; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–103580–02]

RIN 1545–BA53

Noncompensatory Partnership Options

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains a correction to a notice of proposed rulemaking that was published in the **Federal Register** on Wednesday, January 22, 2003 (68 FR 2930) relating to the tax treatment of noncompensatory options and convertible instruments issued by a partnership.

FOR FURTHER INFORMATION CONTACT: Audrey W. Ellis at (202) 622–3060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking that is the subject of this correction is under sections 704(b) and 761 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (REG–103580–02), that was the subject of FR Doc. 03–872, is corrected as follows:

§ 1.704–1 [Corrected]

1. On page 2934, paragraph (b)(0), the third entry in the table is corrected to read as follows:

*	*	*	*	*
Adjustments for non-compensatory options.		1.704–1(b)(2)(iv)(*h*)(*2*)		
*	*	*	*	*