

placed on the Center for Food Safety and Applied Nutrition (CFSAN) Web site at: <http://www.cfsan.fda.gov/~dms/supplmnt.html> when available.

#### FOR FURTHER INFORMATION CONTACT:

Bradford W. Williams, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, telephone: 301-436-1440, FAX: 301-436-2636, e-mail: [Brad.Williams@cfsan.fda.gov](mailto:Brad.Williams@cfsan.fda.gov) for general questions about the downlink and submission of advance questions.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Dietary Supplement Health and Education Act of 1994 (DSHEA) (Public Law 103-417) amended the Federal Food, Drug, and Cosmetic Act to, among other things, provide FDA with express statutory authority to prescribe current good manufacturing practice (CGMP) regulations 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 help ensure that manufacturing, packing, and holding practices will not result in an adulterated or misbranded dietary supplement.

This downlink meeting will provide an opportunity to brief stakeholders on the proposed rule and allow them to ask questions about the proposed rule. It is also intended to fulfill part of the outreach requirements of the Small Business Regulatory Enforcement Fairness Act of 1996. The half-day meeting will focus on information for manufacturers, both large and small, with an emphasis on assistance to small firms. Small firms are encouraged to view and participate in this downlink meeting.

##### II. Agenda

The agenda will include an overview of the proposed rule with the following specific topics: (1) Personnel, (2) physical plant, (3) equipment and utensils, (4) production and process controls, (5) holding and distribution, (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 also will discuss the types of comments and supporting information that would be most helpful to the agency in developing a final rule. Lastly, the meeting will describe how the Small Business Administration (SBA) can help small firms that might be affected by the proposed rule.

The primary intended audience is dietary ingredient and dietary supplement manufacturers, packagers, distributors, and holders, including small businesses, their representatives and consultants; Federal, State and local representatives; and FDA small business representatives and other interested FDA staff. Viewers are encouraged to watch the satellite program and participate in the question and answer periods. Any interested parties with access to a satellite dish may view the downlink directly. For specific technical details, including tuning coordinates, check the CFSAN Web site at: <http://www.cfsan.fda.gov/~dms/supplmnt.html> under "Recent Announcements" before the meeting.

Before the broadcast, we suggest that interested parties read the section in the March 13, 2003 (68 FR 12157), proposed rule entitled "Proposal Highlights and Request for Comments," as well as the background document, fact sheet and the guidance for small businesses that are located at the CFSAN Web site noted above. In addition, a promotional flyer and specific technical tuning instructions will be added to the CFSAN Web site in the near future.

Questions may be submitted in advance of the satellite downlink public meeting until the day before the meeting (see the **FOR FURTHER INFORMATION CONTACT** section of this document).

##### III. Transcripts

A transcript of the program and all questions/answers will be added to docket 96N-0417 and may be examined at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, as well as on the CFSAN Web site. 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 3 weeks after the meeting at a cost of 10 cents per page. In addition, a videotape of the satellite downlink public meeting will be available for viewing after the broadcast at the FDA Dockets Management Branch.

##### IV. Comments

To submit written comments on the proposed rule that published in the **Federal Register** of March 13, 2003, please follow the instructions in the "Request for Comment" section of that document (68 FR 12157 at 12248), a copy of which may be found at CFSAN's Web site at: <http://www.cfsan.fda.gov/~dms/supplmnt.html>.

Dated: April 15, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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#### DEPARTMENT OF LABOR

##### Occupational Safety and Health Administration

##### 29 CFR Parts 1910, 1915, and 1926

[Docket No. S-778-A]

RIN 1218-AB 81

##### Standards Improvement Project—Phase II

**AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.

**ACTION:** Proposed rule; notice of hearing.

**SUMMARY:** On October 31, 2002, OSHA published a proposed rule entitled "Standards Improvement Project—Phase II". OSHA will convene an informal public hearing to receive testimony and documentary evidence relevant to the issues raised in the proposal. This action is in response to the interested parties who have requested the convening of a hearing.

**DATES:** *Informal public hearing.* The Agency will hold an informal public hearing beginning in Washington, DC, on July 8 to July 9, 2003. The hearing will commence at 10 a.m. on the first day, and at 9 a.m. on the second day and subsequent days if they prove necessary; however, the exact daily schedule is at the discretion of the presiding administrative law judge.

*Notice of intention to appear to provide testimony at the informal public hearing.* Interested parties who intend to present testimony at the informal public hearing must notify OSHA of their intention to do so no later than June 5, 2003.

*Hearing testimony and documentary evidence.* Interested parties who will be requesting more than 10 minutes to present their testimony, or who will be submitting documentary evidence at the hearing, must provide the Agency with copies of their full testimony and all