

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 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

documentary evidence they plan to present by June 5, 2003. Parties who provided this material in response to the notice of proposed rulemaking do not have to resubmit their comments and documentary evidence submitted with their comments, but should refer to them in their notice of intention to appear.

ADDRESSES: Informal public hearing.

The informal public hearing to be held in Washington, DC will be located in the Auditorium on the plaza level of the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC.

Notice of intention to appear at the hearing. Notices of intention to appear at the informal public hearing should be submitted in triplicate to the Docket Office, Docket No. S-778-A, Room N-2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Notices may also be faxed to the Docket Office at 202-693-1648 or submitted electronically at <http://ecomments.osha.gov>. OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m.

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 informal public hearing must mail three copies of the testimony and the documentary evidence to the Docket Office at the above address. Testimony may also be faxed to the Docket Office at 202-693-1647. Additional information for submitting testimony and evidence is found under

SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION: For general information and press inquiries, contact Ms. Bonnie Friedman, Director, OSHA Office of Public Affairs, Room N-3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (telephone: (202) 693-1999). For technical inquiries, contact Mr. Robert Manware, Office of Physical Hazards, Room N-3718, (telephone (202) 693-2299; fax: (202) 693-1678) and for hearing information contact Ms. Veneta Chatmon, Office of Information (telephone 202-693-1999) at the above address. For additional copies of this **Federal Register** notice, contact the Office of Publications, Room N-3103, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (telephone (202) 693-1888). Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are

available at OSHA's Home page at <http://www.osha.gov>.

SUPPLEMENTARY INFORMATION: In 1995, the Agency identified a number of provisions in its regulations and standards that were inconsistent, duplicative, outdated, or in need of being rewritten in plain language. In 1998, as part of the process of correcting such provisions, OSHA made several substantive revisions to its health and safety standards that reduced the regulatory obligations of employers while maintaining the safety and health protection afforded to employees (63 FR 33450, June 18, 1998). During and after this rulemaking, the Agency identified several other regulatory provisions in its safety and health standards involving notification of use, frequency of exposure monitoring and medical surveillance, and similar provisions that it believed could be modified to improve the efficiency of compliance and consistency among standards while maintaining health protection for employees. OSHA proposed to make substantive revisions to a number of the health standard provisions identified in this process on October 31, 2002 (67 FR 66494). The period for filing public comment on the proposal was to end on December 30, 2002. Interested parties requested an extension of the deadline for submitting comments based on the need for additional time to provide a thorough review and response to the substantive provisions proposed for revision in the notice. In response to these requests, OSHA extended the period for submitting comments until January 30, 2003 (*see* 68 FR 1023, January 8, 2003). In addition, a number of commenters (Exs. 3-2, 3-16) requested that an informal public hearing be convened on the issues raised in the proposal. OSHA has granted that request and has scheduled an informal public hearing commencing July 8, 2003.

Public Participation—Comments and Hearings

OSHA encourages members of the public to participate in this rulemaking by providing oral testimony and documentary evidence at the informal public hearing that the Agency will convene. In this regard, the Agency invites interested parties having knowledge or experience with respect to the issues raised in the proposal to participate in this process, and welcomes any pertinent data that will provide it with the best available evidence on which to develop the final regulatory requirements.

This section describes the procedures the public must use to schedule an opportunity to deliver oral testimony and provide documentary evidence at the informal public hearing. Notices of intention to appear, hearing testimony and documentary evidence will be available for inspection and copying at the OSHA Docket Office.

Pursuant to section 6(b)(3) of the Act, members of the public will have an opportunity at an informal public hearing to provide oral testimony concerning the issues raised in this proposal. The hearings will commence at 10 a.m. on the first day. At that time, the presiding administrative law judge (ALJ) will resolve any procedural matters relating to the proceeding. The hearings will reconvene on subsequent days at 9 a.m., if necessary.

The legislative history of section 6 of the OSHA Act, as well as OSHA's regulation governing public hearings (29 CFR 1911.15), establish the purpose and procedures of informal public hearings. Although the presiding officer of such hearing is an ALJ, and questions by interested parties is allowed on crucial issues, the proceeding is informal and legislative in purpose. Therefore, the hearing provides interested parties with an opportunity to make effective and expeditious oral presentations in the absence of procedural restraints or rigid procedures that could impede or protract the rulemaking process. In addition, the hearing is an informal administrative proceeding, rather than adjudicative one in which the technical rules of evidence would apply, because its primary purpose is to gather and clarify information. The regulations that govern public hearings, and the pre-hearing guidelines issued for this hearing, will ensure participants fairness and due process, and also will facilitate the development of a clear, accurate and complete record. Accordingly, application of these rules and guidelines will be such that questions of relevance, procedures, and participation generally will favor development of the record.

Conduct of the hearing will conform to the provisions of 29 CFR part 1911, "Rules of Procedure for Promulgating, Modifying, or Revoking Occupational Safety and Health Standards." The regulation at 29 CFR 1911.4 "Additional or Alternative Procedural Requirements," specifies that the Assistant Secretary may, on reasonable notice, issue alternative procedures to expedite proceedings or for other good causes. Although the ALJs who preside over these hearings make no decision or recommendation on the merits of OSHA's proposal, they do have the

responsibility and authority to ensure that the hearing progresses at a reasonable pace and in an orderly manner.

To ensure that interested parties receive a full and fair informal hearing as specified by 29 CFR part 1911, the ALJ has the authority and power to: Regulate the course of the proceedings; dispose of procedural requests, objections, and comparable matters; confine the presentations to matters pertinent to the issues raised; use appropriate means to regulate the conduct of the parties who are present at the hearing; question witnesses, and permit others to question witnesses; and limit the time for such questions. At the close of the hearing, the ALJ will establish a post-hearing comment period for parties who participated in the hearing. During the first part of this period, the participants may submit additional data and information to OSHA, while during the second part of this period, they may submit briefs, arguments, and summations.

Notice of Intention to Appear to Provide Testimony at the Informal Public Hearings. Interested parties who intend to provide oral testimony at the informal public hearings must file a notice of intention to appear by using the procedures specified above in the sections titled **DATES** and **ADDRESSES**. This notice must provide the: Name, address, and telephone number of each individual who will provide testimony; capacity (e.g., name of the establishment/organization the individual is representing; the individual's occupational title and position) in which each individual will testify; approximate amount of time required for each individual's testimony; specific issues each individual will address, including a brief statement of the position that the individual will take with respect to each of these issues; and any documentary evidence the individual will present, including a brief summary of the evidence.

OSHA emphasizes that the hearings are open to the public, and that interested parties are welcome to attend. However, only a party who files a proper notice of intention to appear may ask questions and participate fully in the proceedings. While a party who did not file a notice of intention to appear may be allowed to testify at the hearing if time permits, this determination is at the discretion of the presiding ALJ.

Hearing Testimony and Documentary Evidence. Any party requesting more than 10 minutes to testify at the informal public hearing, or who intends to submit documentary evidence at the

hearing, must, unless already having done so, provide the complete text of the testimony and the documentary evidence as specified above in the sections titled **DATE** and **ADDRESSES**. The Agency will review each submission and determine if the information it contains warrants the amount of time requested. If OSHA believes the requested time is excessive, it will allocate an appropriate amount of time to the presentation, and will notify the participant of this action, and the reasons for the action, prior to the hearing. The Agency may limit to 10 minutes the presentation of any participant who fails to comply substantially with these procedural requirements; in such instances, OSHA may request the participant to return for questions at a later time.

Please note that you may not attach materials such as studies or journal articles to testimony or documentary evidence faxes if they are more than 10 pages long. If you wish to include such materials, you must submit three copies to the OSHA Docket Office at the address listed above. When submitting such materials to the OSHA Docket Office, you must clearly identify your comments by name, date, Docket Number, and subject so that we can attach the materials to your faxed or mailed comments.

Certification of the Record and Final Determination After the Informal Public Hearing. Following the close of the hearing and post-hearing comment period, the presiding ALJ will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health; the record will consist of all of the written comments, oral testimony, and documentary evidence received during the proceeding. However, the ALJ does not make or recommend any decisions as to the content of the final standard. Following certification of the record, OSHA will review the proposed provisions in light of all the evidence received as part of the record, and then will issue the final determinations based on the entire record.

Authority

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, directed the preparation of this document. It is issued under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), Secretary of Labor's Order No. 5-2002 (67 FR 65008) and 29 CFR part 1911.

Signed in Washington, DC on April 16, 2003.

John L. Henshaw,

Assistant Secretary of Labor.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56 and 57

RIN: 1219-AA98 (Phase 6)

Seat Belts for Off-Road Work Machines and Wheeled Agricultural Tractors at Metal and Nonmetal Mines

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Proposed rule; request for comments.

SUMMARY: MSHA is issuing a proposed rule that would update the Agency's requirements for operator restraint systems (seat belts) for off-road work machines and wheeled agricultural tractors at metal and nonmetal mines. The existing standards require seat belts for off-road work machines to meet the requirements of the Society of Automotive Engineers' (SAE) consensus standard SAE J386-1985, and seat belts for wheeled agricultural tractors to meet the requirements of SAE J1194-1983. Since MSHA promulgated these standards, however, the SAE has revised them to reflect technological advances in seat belt design and materials. Seat belts meeting the specifications of earlier versions of these SAE standards are no longer routinely installed by manufacturers. The proposed rule would permit seat belts to meet the requirements of the more recent revisions of the SAE J386 and SAE J1194 standards.

DATES: Submit comments by May 21, 2003.

The incorporation by reference of certain publications in this rule is approved by the Director of the Federal Register as of the effective date of the final rule.

ADDRESSES: Clearly identify comments as such and submit them either electronically to ; by facsimile to 202-693-9441; or by regular mail or hand delivery to MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2352, Arlington, Virginia 22209-3939. Comments are posted for public viewing at <http://www.msha.gov/currentcomments>.

FOR FURTHER INFORMATION CONTACT: Marvin W. Nichols, Director; Office of