

What is the purpose of this Advance Notice of Proposed Rulemaking (ANPRM)?

This ANPRM gives you an opportunity to send us comments and suggestions on whether and how we might revise the listings and other criteria in sections 8.00 and 108.00 for evaluating skin disorders. We last published final rules revising the criteria that we use to evaluate skin disorders on June 9, 2004, 69 FR 32260. We are publishing this ANPRM as part of our ongoing effort to ensure that our criteria reflect the latest advances in medicine.

On which rules are we inviting comments and suggestions?

You can find our current rules on which we are inviting comments and suggestions on the Internet at the following locations:

- Sections 8.00 and 108.00 are in the Listing of Impairments in appendix 1 to subpart P of part 404 of our regulations at http://www.ssa.gov/OP_Home/cfr20/404/404-ap10.htm or at <http://www.ssa.gov/disability/professionals/bluebook/>.

Who should send us comments and suggestions?

We invite comments and suggestions from people who apply for or receive benefits from us, members of the general public, advocates and organizations who represent people who have skin disorders, State agencies that make disability determinations for us, experts in the evaluation of skin disorders, and researchers.

What should you comment about?

We are interested in any comments and suggestions on how we might revise sections 8.00 and 108.00 of our listings. For example, we are interested in knowing if:

- You have concerns about any of the provisions in the current skin impairments listings, such as whether you believe we should change any of our criteria or whether you believe a listing is difficult to use or to understand.
- You would like to see our skin impairments listings include something that is not there now, such as other skin disorders, additional medical technologies, specific laboratory studies, or new medical criteria.
- You believe our skin impairments listings should include functional criteria and, if so, what those criteria should be.

Will we respond to your comments from this notice?

We will not respond directly to the comments you send in response to this ANPRM. After we have considered all comments and suggestions, as well as information about advances in medical knowledge, treatment, and methods of evaluating skin disorders, and our program experience using the current listings, we will determine whether we should revise any of the listings or other criteria in sections 8.00 or 108.00. If we decide to propose specific revisions, we will publish a Notice of Proposed Rulemaking in the **Federal Register** and you will have a chance to comment on the revisions we propose.

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: September 28, 2009.

Michael J. Astrue,

Commissioner of Social Security.

[FR Doc. E9-27033 Filed 11-9-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 4

[Docket No. FDA-2009-N-0435]

Current Good Manufacturing Practice Requirements for Combination Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to February 5, 2010, the comment period for the proposed rule that appeared in the **Federal Register** of September 23, 2009. In the proposed rule, FDA requested comments on current good manufacturing practice (CGMP) requirements applicable to combination products. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: The comment period for the proposed rule published September 23, 2009 (74 FR 48423), is extended. Submit electronic or written comments by February 5, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2009-N-0435, by any of the following methods: *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products (HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, Suite 200, Rockville, MD 20855 301-427-1934.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 2009 (74 FR 48423), FDA published a proposed rule with a 90-day comment period to request comments on CGMP requirements applicable to combination products. Comments on the proposed rule will inform FDA's rulemaking to establish regulations for current good manufacturing practices for combination products.

The agency has received requests for a 45-day extension of the comment period for the proposed rule. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 45 days, until February 5, 2010. The agency believes that a 45-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 4, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

RIN 1218-AC41

Combustible Dust

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

ACTION: Notice of stakeholder meetings.

SUMMARY: OSHA invites interested parties to participate in informal stakeholder meetings on the workplace hazards of combustible dust. OSHA plans to use the information gathered at these meetings in developing a proposed standard for combustible dust.

DATES: Dates and locations for the stakeholder meetings are:

- December 14, 2009, at 9 a.m., in Washington, DC.
- December 14, 2009, at 1 p.m., in Washington, DC.

- Additional meetings are planned for early 2010, and will be announced in one or more subsequent notices.

ADDRESSES:

I. Registration

Submit your notice of intent to participate in one of the scheduled or future stakeholder meetings by one of the following:

- *Electronic.* Register at <https://www2.ergweb.com/projects/conferences/osha/register-osha-stakeholder.htm> (follow the instructions online).

- *Facsimile.* Fax your request to: (781) 674-2906, and label it "Attention: OSHA Combustible Dust Stakeholder Meeting Registration."

- *Regular mail, express delivery, hand (courier) delivery, and messenger service.* Send your request to: ERG, Inc., 110 Hartwell Avenue, Lexington, MA 02421; Attention: OSHA Combustible Dust Stakeholder Meeting Registration.

II. Meetings

The December 14, 2009, meetings will be held at the Marriott at Metro Center, 775 12th Street, NW., Washington, DC, 20005.

The 2010 meeting dates and locations will be announced in one or more subsequent notices.

FOR FURTHER INFORMATION CONTACT:

Information regarding this notice is available from the following sources:

- *Press inquiries.* Contact Jennifer Ashley, Director, OSHA Office of Communications, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693-1999.

- *General and technical information.* Contact Don Pittenger, Director, Office of Safety Systems, OSHA Directorate of Standards and Guidance, Room N-3609, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693-2255.

- *Copies of this Federal Register notice.* Electronic copies are available at <http://www.regulations.gov>. This **Federal Register** notice, as well as news releases and other relevant information, also are available on the OSHA Web page at <http://www.osha.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The hazards of combustible dust encompass a wide array of materials, industries, and processes. Any combustible material can burn rapidly when in a finely divided form. Materials that may form combustible dust include, but are not limited to, wood, coal, plastics, biosolids, candy, sugar, spice,

starch, flour, feed, grain, fertilizer, tobacco, paper, soap, rubber, drugs, dried blood, dyes, certain textiles, and metals (such as aluminum and magnesium). Industries that may have combustible dust hazards include, among others: Animal food manufacturing, grain handling, food manufacturing, wood product manufacturing, chemical manufacturing, textile manufacturing, furniture manufacturing, metal processing, fabricated metal products and machinery manufacturing, pesticide manufacturing, pharmaceutical manufacturing, tire manufacturing, production of rubber and plastics, plastics and rubber products manufacturing, recycling, wastewater treatment, and coal handling.

OSHA is developing a standard that will comprehensively address the fire and explosion hazards of combustible dust. The Agency has issued an Advanced Notice of Proposed Rulemaking (ANPR) (74 FR 54334) requesting comments, including data and other information, on issues related to the hazards of combustible dust in the workplace. OSHA plans to use the information received in response to the ANPR and at the stakeholder meetings in developing a proposed standard for combustible dust.

II. Stakeholder Meetings

The stakeholder meetings will be conducted as a group discussion on views, concerns, and issues surrounding the hazards of combustible dust. To facilitate as much group interaction as possible, formal presentations will not be permitted. Formal input should be submitted as indicated in the ANPR referenced earlier in this notice. OSHA believes the stakeholder meeting discussion should center on major issues such as:

- Possible regulatory approaches.
- Scope.
- Organization of a prospective standard.
- The role of consensus standards.
- Economic impacts.
- Additional topics as time permits.

OSHA plans to hold additional meetings in the early part of 2010, after the ANPR comment period has closed and the Agency has begun to analyze the comments received. One or more additional notices will be published with the information for those meetings. Stakeholders interested in participating in a 2010 meeting may express their intent through one of the methods specified in the **ADDRESSES** section of this notice under Registration. You will be contacted regarding the dates and locations of the future meetings.