

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at <http://www.gpoaccess.gov/fr/index.html>.

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 update and revise the listings and other criteria in sections 10.00 and 110.00 for evaluating impairments that affect multiple body systems. We last published final rules revising the criteria that we use to evaluate impairments that affect multiple body systems on August 30, 2005. 70 FR 51252. 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 10.00 and 110.00 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 impairments that affect multiple body systems, State agencies that make disability determinations for us, experts in the evaluation of impairments that affect multiple body systems, and researchers.

What should you comment about?

We are interested in any comments and suggestions on how we might revise sections 10.00 and 110.00 of our listings. For example, we are interested in knowing if:

- You have concerns about any of the provisions in the current impairments that affect multiple body systems 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 impairments that affect multiple body systems listings include something that

is not currently included, such as other impairments, additional medical technologies, specific laboratory studies, or new medical criteria.

- You believe our impairments that affect multiple body systems listings should include functional criteria and 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 impairments that affect multiple body systems, and our program experience using the current listings, we will determine whether we should revise any of the listings or other criteria in sections 10.00 or 110.00. 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. E9-27031 Filed 11-9-09; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA 2009-0057]

RIN 0960-AG91

Revised Medical Criteria for Evaluating Skin Disorders

AGENCY: Social Security Administration.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: We are requesting your comments on whether and how we should revise the criteria in our Listing of Impairments (the listings) for evaluating skin disorders in adults and children. We are requesting your comments as part of our ongoing effort to ensure that our listings reflect current medical knowledge. If we propose specific revisions, we will publish a Notice of Proposed Rulemaking in the **Federal Register**.

DATES: To be sure that we consider your comments, we must receive them by no later than January 11, 2010.

ADDRESSES: You may submit comments by any one of three methods—Internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA-2009-0057 so that we may associate your comments with the correct regulation.

Caution: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. **Internet:** We strongly recommend that you submit your comments via the Internet. Please visit the Federal eRulemaking portal at <http://www.regulations.gov>. Use the *Search* function to find docket number SSA-2009-0057. The system will issue a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. **Fax:** Fax comments to (410) 966-2830.

3. **Mail:** Mail your comments to the Office of Regulations, Social Security Administration, 137 Altmeier Building, 6401 Security Boulevard, Baltimore, Maryland 21235-6401.

Comments are available for public viewing on the Federal eRulemaking portal at <http://www.regulations.gov> or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Jane Deweib, Social Insurance Specialist, Office of Medical Listings Improvement, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 965-1020. For information on eligibility or filing for benefits, call our national toll-free number, 1-800-772-1213 or TTY 1-800-325-0778, or visit our Internet site, Social Security Online, at <http://www.socialsecurity.gov>.

SUPPLEMENTARY INFORMATION:

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at <http://www.gpoaccess.gov/fr/index.html>.

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.

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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.