

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 111**

[Docket No. 2007N-0186]

RIN 0910-AB88

**Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Extension of Comment Period****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Interim final rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to October 24, 2007, the comment period for the interim final rule (IFR) that appeared in the *Federal Register* of June 25, 2007 (72 FR 34959). In the IFR, FDA requested comments on a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit written and electronic comments by October 24, 2007.**ADDRESSES:** You may submit comments, identified by Docket No. 2007N-0186, and/or Regulation Identifier Number (RIN) 0910-AB88, by any of the following methods:**Electronic Submissions**

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow the instructions for submitting comments on the agency Web site.

**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 or the agency Web site, as described previously in the **ADDRESSES** portion of this document under *Electronic Submissions*.

**Instructions:** All submissions received must include the agency name and Docket No(s). and/or RIN for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, 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.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), 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:**

Vasilios Frankos, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1696.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the *Federal Register* of June 25, 2007 (72 FR 34959), FDA published an IFR with a 90-day comment period to request comments on a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. Comments on the exemption procedure will provide an opportunity for interested persons to comment on whether this exemption procedure should be modified, and if so, whether there is any additional information that may be helpful to articulate with respect to what a petition needs to show that may inform future guidance.

The agency has received a request for a 60-day extension of the comment period for the IFR. The request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the IFR.

FDA has considered the request and is extending the comment period for the IFR for 30 days, until October 24, 2007. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic 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: September 11, 2007.

**Jeffrey Shuren,***Assistant Commissioner for Policy.*

[FR Doc. E7-18293 Filed 9-14-07; 8:45 am]

**BILLING CODE 4160-01-S****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Indian Health Service****25 CFR Part 900****Contracts Under the Self-Determination and Education Assistance Act; Change of Address for the Claims Branch****AGENCY:** Indian Health Service (IHS).**ACTION:** Final Rule; change of address.

**SUMMARY:** The Indian Health Service is amending its regulations governing contracts under the Indian Self-Determination and Education Assistance Act to reflect a change of address due to the relocation of the Claims Branch.

**DATES:** This rule change is effective September 17, 2007.**FOR FURTHER INFORMATION CONTACT:**

Hankie Ortiz, Acting Director, Division of Regulatory Affairs, IHS, 801 Thompson Avenue, Twinbrook Metro Plaza, Suite 450, Rockville, Maryland 20852, Telephone (301) 443-1116.

**SUPPLEMENTARY INFORMATION:****I. Background**

Regulations promulgated by the IHS to govern the administration of contracts under the Indian Self-Determination and Education Assistance Act reference a mailing address for the Claims Branch. The Claims Branch has moved its office to a new location. This action provides the new mailing address for filing medical-related claims with the Claims Branch.

## II. Procedural Requirements

### A. Determination To Issue Final Rule Effective in Less than 30 Days

IHS has determined that the public notice and comment provisions of the Administrative Procedure Act, 5 U.S.C. 553(b) do not apply to this rulemaking. The changes being made relate solely to procedure and practice. The changes therefore, meet the requirements for exemption from notice and comment in 5 U.S.C. 553(b)(A).

### B. Review Under Procedural Statutes and Executive Orders

IHS has reviewed this rule under the following statutes and Executive Orders governing rulemaking procedures: The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*; the Regulatory Flexibility Enforcement Act, 5 U.S.C. 601 *et seq.*; the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801 *et seq.*; the Paperwork Reduction Act, 4 U.S.C. 3501 *et seq.*; Executive Order 12630 (Takings); Executive Order 12866 (Regulatory Planning and Review); Executive Order 12988 (Civil Justice Reform); Executive Order 13132 (Federalism); Executive Order 13175 (Tribal Consultation); and Executive Order 13211 (Energy Impacts). IHS has determined that this rule does not trigger any of the procedural requirements of those statutes and Executive Orders, since this rule is technical in nature and merely changes the mailing address for the Claims Branch.

### List of Subjects in 25 CFR Part 900

Administrative practice and procedure, Buildings and facilities, Claims, Government contracts, Government property management, Grant programs—Indians, Health care, Indians, Indians—business and finance.

■ For the reasons stated in the preamble, IHS amends its regulation in 25 CFR Part 900 as follows:

#### **PART 900—FEDERAL TORT CLAIMS ACT COVERAGE GENERAL PROVISIONS PROCEDURE FOR FILING MEDICAL-RELATED CLAIM**

■ 1. The authority citation for part 900 continues to read as follows:

*Authority:* 25 U.S.C. 450f *et seq.*

#### **§ 900.201 [Amended]**

■ 2. Section 900.201 is amended by removing “Chief, PHS Claims Branch,

Room 18–20, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857” and adding in its place Office of the General Counsel, General Law Division, Claims Office, 330 Independence Avenue, SW, Room 4256, Wilbur J. Cohen Federal Building, Washington, DC 20201.”

Dated: September 5, 2007.

**Robert G. McSwain,**

*Deputy Director, Indian Health Service.*

[FR Doc. 07–4585 Filed 9–14–07; 8:45 am]

**BILLING CODE 4165–16–M**

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 52**

**[EPA–R09–OAR–2007–0276; FRL–8456–4]**

### **Revisions to the California State Implementation Plan, Mojave Desert Air Quality Management District**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve a revision to the Mojave Desert Air Quality Management District (MDAQMD) portion of the California State Implementation Plan (SIP). This revision concerns volatile organic compound (VOC) emissions from the usage of solvents. We are approving a local rule that regulates these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

**DATES:** This rule is effective on November 16, 2007 without further notice, unless EPA receives adverse comments by October 17, 2007. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

**ADDRESSES:** Submit comments, identified by docket number R09–OAR–2007–0276, by one of the following methods:

1. *Federal eRulemaking Portal:* [www.regulations.gov](http://www.regulations.gov). Follow the on-line instructions.

2. *E-mail:* [steckel.andrew@epa.gov](mailto:steckel.andrew@epa.gov).

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

*Instructions:* All comments will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov),

including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through [www.regulations.gov](http://www.regulations.gov) or e-mail. [www.regulations.gov](http://www.regulations.gov) is an “anonymous access” system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

*Docket:* The index to the docket for this action is available electronically at [www.regulations.gov](http://www.regulations.gov) and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Allen, EPA Region IX, (415) 947–4120, [allen.cynthia@epa.gov](mailto:allen.cynthia@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document, “we,” “us” and “our” refer to EPA.

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#### **I. The State’s Submittal**

##### *A. What rule did the State submit?*

Table 1 lists the rule we are approving with the date that the amended rule was adopted by the local air agency and submitted by the California Air Resources Board (CARB).