maintained for at least 5 years from the date of exportation. The records shall be made available to the Food and Drug Administration (FDA), upon request, during an inspection for review and copying by FDA.

(1) Records demonstrating that the product meets the foreign purchaser's specifications. Such records shall include descriptions or lists of product specifications requested by the foreign purchaser, such as product details (e.g., dosage strength, dosage form, purity, quality, operating parameters, composition, etc.) and manufacturing specifications requested by the foreign purchaser (e.g., type of sterilization process to be used, compliance with a particular manufacturing standard, etc.);

(2) Records demonstrating that the product does not conflict with the laws of the importing country, such as a letter from an appropriate foreign government agency, department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws. Letters or other documents from nongovernmental bodies or persons, such as company officials or attorneys in the foreign country, are not acceptable. If the letter or other document from the foreign government is not in English, the person exporting the article must have an English-language translation of that document or be prepared to translate the document into English at the time of any FDA inspection;

(3) Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export, including copies of any labels or labeling statements, such as ''For export only,'' that are placed on the shipping packages; and

(4) Records demonstrating that the product is not sold or offered for sale in the United States, such as documentation concerning the product, its labeling, and similar products sold in the United States.

(c) *Additional recordkeeping requirements for partially processed biologics exported under section 351(h) of the Public Health Service Act.* In addition to the requirements in paragraph (b) of this section, persons exporting a partially processed biologic under section 351(h) of the Public Health Service Act shall maintain, for at least 5 years from the date of exportation and make available to FDA, upon request, during an inspection for review and copying by FDA, the following records:

(1) Records demonstrating that the product for export is a partially processed biological product and not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) Records that demonstrate that the partially processed biological product was manufactured in conformity with current good manufacturing practice requirements;

(3) Distribution records of the exported partially processed biological products; and

(4) Copies of all labeling that accompanies the exported partially processed biological product, such as a container label with the statement, ''Caution: For Further Manufacturing Use Only'' and any package insert.

(d) *Notification requirements for drugs, biologics, and devices exported under section 802 of the Federal Food, Drug, and Cosmetic Act.* (1) Persons exporting a human drug, biologic, or device under section 802 of the Federal Food, Drug, and Cosmetic Act, other than a drug or a device for investigational use exported under section 802(c) of the Federal Food, Drug, and Cosmetic Act, shall provide written notification to the Food and Drug Administration. The notification shall identify:

(i) The product's name;

(ii) If the product is a drug or biologic, the product's generic name or, if the product is a device, the type of device;

(iii) If the product is a drug or biologic, a description of the product's strength and dosage form or, if the product is a device, the product's model number; and

(iv) The country that is to receive the exported article.

(2) The notification shall be sent to the following addresses:

(i) For biological drug products and devices regulated by the Center for Biologics Evaluation and Research—Division of Case Management (HFM–610), Office of Compliance, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, rm. 200N, Rockville, MD 20852–1448;

(ii) For human drug products—Division of Labeling and Nonprescription Drug Compliance (HFD–310), Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855–2737;

(iii) For devices—Division of Program Operations (HFZ–305), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

(e) *Recordkeeping requirements for products subject to section 802(g) of the act.* (1) Any person exporting a product under any provision of section 802 of the act shall maintain records of all drugs, biologics, and devices exported and the countries to which the products were exported. In addition to the requirements in paragraph (b) of this section, such records include, but are not limited to, the following:

(i) The product's name;

(ii) If the product is a drug or biologic, the product's generic name or, if the product is a device, the type of device;

(iii) If the product is a drug or biologic, a description of its strength and dosage form and the product's lot or control number or, if the product is a device, the product's model number;

(iv) The consignee's name and address; and

(v) The date on which the product was exported and the quantity of product exported.

(2) These records shall be kept at the site from which the products were exported and be maintained at least 5 years after the date of exportation. The records shall be made available to FDA, upon request, during an inspection for review and copying by FDA.

Dated: December 23, 1998.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8159 Filed 4–1–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 99N–0554]

Implementation of the Food and Drug Administration Modernization Act; Provisions for Use in Food Labeling of Health Claims and Nutrient Content Claims Based on Authoritative Statements; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of March 24, 1999 (56 FR 14178). This document announced a forthcoming public meeting concerning implementation of sections 303 and 304 of the FDA Modernization Act of 1997. The document published with an incorrect title. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy (HF–

27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

In FR Doc. 99–7115, appearing on page 14178 in the **Federal Register** of March 24, 1999, the following correction is made:

On page 14178, in the second column, the title ''How to Use Health Claims and Nutrient Content Claims in Food Labeling; Public Meeting'' is corrected to read ''Implementation of the Food and Drug Administration Modernization Act; Provisions for Use in Food Labeling of Health Claims and Nutrient Content Claims Based on Authoritative Statements; Public Meeting''.

Dated: March 25, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8094 Filed 4–1–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010–AC09

Workshops on Proposed Rule—Establishing Oil Value for Royalty Due on Federal Leases

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of extended workshops.

SUMMARY: The Minerals Management Service is extending the April 6, 1999, Federal oil royalty valuation workshop (Workshop 3). On March 12, 1999 (64 FR 12267), MMS announced it would reopen the comment period and hold three workshops to discuss unresolved issues pertaining to the proposed Federal oil valuation rule. The workshops were scheduled in Houston, Texas, March 24; Albuquerque, New Mexico, March 25; and Washington, D.C., April 6. Based on the various proposals and questions that surfaced during the Houston and Albuquerque workshops, the workshop participants agreed that additional time would be needed to resolve those questions and evaluate the proposals. Therefore, MMS is extending the workshop in Washington, D.C., to 2 days.

DATES: April 6–7, 1999, beginning at 9 a.m. and ending 5 p.m. Eastern time.

ADDRESSES: Workshop 3 will be held at the Main Interior Building, 1849 C Street, N.W., Washington, D.C. 20240 (large buffet room adjacent to the cafeteria in the basement). Phone: (202) 208–3512.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Publications Staff, Minerals Management Service, Royalty Management Program, P.O. Box 25165, MS 3021, Denver, Colorado 80225–0165, telephone (303) 231–3432, fax number (303) 231–3385, e-Mail David.Guzy@mms.gov.

SUPPLEMENTARY INFORMATION: The workshops will be open to the public without advance registration. Public attendance may be limited to the space available. We encourage a workshop atmosphere; members of the public are encouraged to participate in a discussion of the alternatives. For building security measures, each person may be required to present a picture identification to gain entry to the meetings.

Dated: March 29, 1999.

Dale Fazio,

Acting Associate Director for Royalty Management.

[FR Doc. 99–8132 Filed 4–1–99; 8:45 am]

BILLING CODE 4310–MR–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 195–0101b FRL–6235–7]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision, Yolo-Solano Air Quality Management District, Monterey Bay Unified Air Pollution Control District, South Coast Air Quality Management District, Santa Barbara County Air Pollution Control District, Sacramento Metropolitan Air Quality Management District, and Kern County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP) which concern the control of volatile organic compound (VOC) emissions from organic solvent cleaning, and surface preparation and clean-up.

The intended effect of proposing approval of these rules is to regulate emissions of VOCs in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). In the Final Rules Section of this **Federal Register**, the EPA is approving the state's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no adverse comments are received, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will not take effect and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by May 3, 1999.

ADDRESSES: Written comments should be addressed to: Andrew Steckel, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rule revisions and EPA's evaluation report of each rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule revisions are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812

Yolo-Solano Air Quality Management District, 1947 Galileo Court, Suite 103, Davis, CA 95616

Monterey Bay Unified Air Pollution Control District, 24580 Silver Cloud Court, Monterey, CA 93940

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765

Santa Barbara County Air Pollution Control District, 26 Castilian Drive B–23, Goleta, CA 93117

Sacramento Air Quality Management District, 8411 Jackson Road, Sacramento, CA 95826

Kern County Air Pollution Control District, 2700 M Street, Suite 302, Bakersfield, CA

FOR FURTHER INFORMATION CONTACT: Andrew Steckel, Rulemaking Office, (AIR–4), Air Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105–3901, Telephone: (415) 744–1185.

SUPPLEMENTARY INFORMATION:

This document concerns Yolo-Solano Air Quality Management District Rule 2.31—Surface Preparation and Cleanup, Monterey Bay Unified Air Pollution Control District Rule 433—Organic Solvent Cleaning, South Coast Air Quality Management District Rule 1122—Solvent Degreasers, Santa Barbara County Air Pollution Control