

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 314 be amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e).

2. Section 314.420 is amended by removing and reserving paragraph (a)(1), and by revising the second sentence of paragraph (a)(5) to read as follows:

§ 314.420 Drug master files.

(a) * * *

(1) [Reserved]

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(5) * * * (A person wishing to submit information and supporting data in a drug master file (DMF) that is not covered by Types II through IV DMF's must first submit a letter of intent to the Drug Master File Staff, Food and Drug Administration, 12420 Parklawn Dr., rm. 2-14, Rockville, MD 20857. * * *)

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Dated: June 26, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-16206 Filed 6-30-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR**Bureau of Indian Affairs****25 CFR Chapter I****Meeting of the Indian Self-Determination Negotiated Rulemaking Committee**

AGENCY: Bureau of Indian Affairs, Interior Indian Health Service, HHS.

ACTION: Notice of meeting.

SUMMARY: The Secretary of the Interior (DOI) and the Secretary of Health and Human Services (DHHS) have established an Indian Self-Determination Negotiated Rulemaking Committee (Committee) to negotiate and develop a proposed rule implementing the Indian Self-Determination and

Education Assistance Act (ISDEEA), as amended.

The Departments have determined that the establishment of this Committee is in the public interest and will assist the agencies in developing regulations authorized under section 107 of the ISDEEA. The agenda for this meeting will consist of workgroup reports on the advantages and disadvantages of developing regulations in those subject areas provided in ISDEEA where regulations are permitted. In addition, further meeting and work assignments will be planned.

DATES: The Committee and appropriate workgroups will meet on the following days beginning at approximately 8:30 am and ending at approximately 5:00 pm on each day: Sunday, July 9, Monday, July 10, Tuesday, July 10, Wednesday, July 12, Thursday, July 13.

ADDRESSES: All meetings July 9 through July 13, 1995, will be held at the Red Lion Hotel, 3203 Quebec Street, Denver, CO 80207. Tel.: (303) 321-3333. (Workgroups will also be meeting at the same location.)

It was originally planned that this meeting be held in Oklahoma City, however, organizers were unable to find adequate accommodations in Oklahoma City or Tulsa. Due to the lack of space at these preferred locations, the site for the meeting has been changed to Denver Colorado. Also the difficulty of confirming a meeting location in Oklahoma has made it necessary that this notice be published within the prescribed 15 days of the actual beginning of the meeting. Committee activities begin on Sunday, July 9, and will continue through Thursday, July 13. Activities will include meetings of the full committee as well as various workgroup sessions.

Written statements may be submitted to Mr. James J. Thomas, Chief, Division of Self-Determination Services, Bureau of Indian Affairs, 1849 C Street, NW, MS: 4627-MIB, Washington, DC 20240, telephone (202) 208-3708.

FOR FURTHER INFORMATION CONTACT: Mr. James J. Thomas, Chief, Division of Self-Determination Services, Bureau of Indian Affairs, 1849 C Street, NW., MS: 4627-MIB, Washington, DC 20240, telephone (202) 208-3708; or Mrs. Merry Elrod, Acting Director, Division of Self-Determination, Indian Health Service, 5600 Fishers Lane, Parklawn Building, Room 6A-05, Rockville, MD 20857, telephone (301) 443-1044.

SUPPLEMENTARY INFORMATION: The location and dates of future meetings will be published in the **Federal Register**. The meetings will be open to

the public without advanced registration.

Public attendance may be limited to the space available. Members of the public may make statements during the meeting, to the extent time permits and file written statements with the Committee for its consideration. Written statements should be submitted to the address listed above. Summaries of Committee meetings will be available for public inspection and copying ten days following each meeting at the same address. In addition, the materials received to date during the input sessions are available for inspection and copying at the same address.

Dated: June 28, 1995.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 95-16351 Filed 6-30-95; 8:45 am]

BILLING CODE 4310-02-M

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 52 and 70**

[CA 147-2-7073; AD-FRL-5253-2]

Clean Air Act Proposed Interim Approval of the Operating Permits Program; Proposed Approval of State Implementation Plan Revision for the Issuance of Federally Enforceable State Operating Permits; Mojave Desert Air Quality Management District, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes interim approval of the title V operating permits program submitted by the Mojave Desert Air Quality Management District (Mojave Desert, or District) for the purpose of complying with federal requirements that mandate that states develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources. There are nine deficiencies in Mojave Desert's program, as specified in the Technical Support Document and outlined below, that must be corrected before the program can be fully approved. EPA is also proposing to approve a revision to Mojave Desert's portion of the California State Implementation Plan (SIP) regarding synthetic minor regulations for the issuance of federally enforceable state operating permits (FESOP). In order to extend the federal enforceability of state operating permits to hazardous air pollutants (HAP), EPA