

3. The party's participation would promote a balance of interests being represented at the conference.

4. The party's participation would promote the consideration and discussion of a variety of issues raised during the rule review process.

5. The party has experience or expertise in activities affected by the Franchise Rule.

6. The party adequately reflects the views of the affected interest(s).

7. The number of parties selected will not be so large as to inhibit effective discussion among them.

The conference will be facilitated by a Commission staff member. It will be held over the course of three consecutive days, September 12-14, 1995, at the Crown Sterling Suites, 7901 34th Avenue South, Bloomington, Minnesota. Parties interested in representing an affected interest at the conference must notify Commission staff in writing on or before August 11, 1995. Each notice of interest in participating at the conference should contain a brief statement making clear which affected interest the requestor seeks to represent. Prior to the conference, parties selected to represent an affected interest will be provided with copies of the comments submitted in response to the request for comments.

List of Subjects in 16 CFR Part 436

Advertising, Business and industry, Franchising, Trade practices

Authority: 15 U.S.C. 41-58.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 95-16257 Filed 6-30-95; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 94N-0449]

New Drug Applications; Drug Master Files

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise its regulations governing drug master files (DMF's), which are referred to in the review and approval of new drugs and antibiotic drugs for human use. A DMF is a voluntary submission

to FDA that may be used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The information contained in a DMF may be referred to in support of an investigational new drug application (IND), a new drug application (NDA), an abbreviated new drug application (ANDA), or amendments or supplements to any of these. FDA has defined five distinct categories of submissions that it will accept and maintain, and it has designated these as Type I through Type V DMF's.

In December 1992, the Center for Drug Evaluation and Research's (CDER's) Chemistry, Manufacturing, Controls Coordinating Committee (CMCCC) established a DMF Task Force to perform a review and to explore ways of improving all aspects of the system. One of the Task Force recommendations, which was adopted by the CMCCC, was to eliminate Type I DMF's. Type I DMF's contain information about manufacturing sites, facilities, operating procedures, and personnel. The Task Force concluded that Type I DMF's should be eliminated because they contain outdated information, duplicate information contained in marketing applications, and are not used by CDER's review divisions or FDA's field inspectors. Under the proposed rule, FDA would no longer permit information submitted in a Type I DMF to be incorporated by reference in IND's, NDA's, ANDA's, abbreviated antibiotic applications (AADA's), and supplemental applications. This proposed rule is intended to eliminate submissions of information that are not necessary either to conduct inspections of manufacturing facilities or to review the chemistry, manufacturing, and controls sections of IND's, NDA's, and abbreviated applications. This proposed rule would not apply to master file systems that are operated by the Center for Biologics Evaluation and Research, the Center for Veterinary Medicine, and Center for Device and Radiological Health.

DATES: Written comments by October 2, 1995. FDA proposes that any final rule based on this proposal become effective 60 days after its date of publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drug

Evaluation and Research (HFD-362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1046.

SUPPLEMENTARY INFORMATION:

I. Introduction

DMF's allow regulated industry to submit to FDA information that may be used to support an IND, NDA, ANDA, AADA, another DMF, an export application, or amendments or supplements to any of these. FDA does not require industry to submit DMF's; a DMF is submitted solely at the discretion of the holder. DMF's allow industry to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of drugs for human use. This information is then incorporated by reference in a drug application or supplement without public disclosure.

FDA regulations in § 314.420(a) (21 CFR 314.420(a)) define five types of DMF's according to the kind of information to be submitted. Type I submissions include manufacturing site, facilities, operating procedures, and personnel information. Type II submissions include information regarding drug substances, drug substance intermediates, and materials used to prepare them, or drug products. Type III submissions include information about packaging material. Type IV submissions include information concerning excipients, colorants, flavors, and essences, or material used in their preparation. Type V submissions, detailed in the "Guideline for Drug Master Files" (1989), include FDA-accepted reference information.

Under § 314.420, FDA recommended that foreign drug manufacturing facilities file with FDA information concerning their manufacturing sites, facilities, operating procedures, and personnel in a Type I DMF. FDA requested this information to plan its on-site inspections of and travel to foreign drug manufacturing facilities. FDA believed that inspections would be conducted more efficiently if FDA inspectors knew in advance the location, plant layout, equipment type, and personnel at the foreign manufacturing site. FDA did not request that domestic firms submit Type I DMF's because FDA inspectors regularly visit firms in their district and are familiar with both their personnel and manufacturing sites. Nonetheless, some domestic pharmaceutical firms have submitted Type I DMF's. Currently, CDER has approximately 1,700 Type I DMF's.

Recently, FDA evaluated the usefulness of Type I DMF's. The agency determined that its inspectors were not using Type I DMF's to plan foreign inspections because the Type I DMF was not easily accessible or information contained in the Type I DMF was outdated. Instead, FDA now requests foreign firms to submit a preinspection document package that includes both current facility and product-specific information. FDA inspectors use the preinspection package to plan their inspection. Although submission of the package is voluntary, foreign firms comply with the agency's request because the information helps inspectors to conduct inspections quickly and efficiently. The agency concluded that Type I DMF's could be eliminated without adversely affecting inspections of foreign manufacturing facilities.

FDA has also determined that its review divisions do not rely on Type I DMF's. Although Type I DMF's are often incorporated by reference into IND's, NDA's, and abbreviated applications, the information that the agency requested to be submitted under Type I DMF's is not required for chemistry, manufacturing, and controls review. Under 21 CFR 314.50(d)(1)(i) and (d)(1)(ii), a drug product applicant is required to furnish the name and location of facilities used in the manufacture of the drug substance or product. Unlike a Type I DMF submission, this information, when submitted as part of an application, is current and product-specific. Therefore, review divisions rely on the applications themselves for this information.

Accordingly, the agency proposes to amend § 314.420 to eliminate Type I DMF's. The agency would no longer accept new Type I DMF's, or correspondence updating existing Type I DMF's. The information in Type I DMF's currently on file could no longer be incorporated by reference into new applications, amendments, or supplements, and the Type I DMF's would be transferred to the Federal Records Center, Suitland, MD. These proposed changes would supersede all information regarding Type I DMF's detailed in the "Guideline for Drug Master Files."

The agency acknowledges that some firms may have submitted information under a Type I DMF that should have been filed under Types II through V DMF's. Therefore, FDA is proposing to make available a list of all CDER Type I DMF's for public review in the Dockets Management Branch under the docket number found in brackets in the

heading of this document. If a DMF holder believes that its Type I DMF should be categorized as another type of DMF, the DMF holder should submit a request to the Drug Master File Staff, Food and Drug Administration, rm. 2-14, 12420 Parklawn Dr., Rockville, MD 20857, within 30 days of publication of any final rule based on this proposal. This request should: (1) Be submitted by the responsible official or designated U.S. agent; (2) briefly identify the subject of the DMF; and (3) propose the DMF Type (i.e., Type II, III, IV, or V) to which information in the Type I DMF should be transferred. If the information should be incorporated into an existing Type II through Type V DMF, the file number of that DMF should be provided. FDA would consider transferring an entire Type I DMF to another type only if the Type I DMF contains substantive information other than information concerning manufacturing site, facilities, operating procedures, and personnel.

The agency also recognizes that some Type I DMF's currently on file contain information concerning sterilization process validation and other information relevant to the review, evaluation, and assurance of the sterility of sterile products. For sterile items that are not the subject of an IND, NDA, ANDA, or AADA, and that are sold to a second party (e.g., rubber closures that are sterilized by the manufacturer and sold to a second party), CDER would consider transferring product-specific and general information concerning sterilization process validation to the DMF file or DMF type (i.e., II through IV) under which manufacturing information for the specific item is filed. Contract manufacturers of sterile finished drug products, contract sterilization firms (e.g., ethylene oxide, gamma radiation, and electron beam radiation), and manufacturers of sterile finished drug products that are the subject of a drug product application could request a transfer from Type I to Type V DMF of nonproduct-specific information and procedures that are submitted to support a claim of sterility. Where applicable, the content and format of such transferred information should follow FDA's guideline entitled "Guideline for Submitting Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products." The mechanism for requesting a transfer would be the same as the mechanism for recategorizing Type I DMF's, as described in the preceding paragraph.

II. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed regulation, if finalized, would lighten paperwork and recordkeeping burdens, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Effective Date

FDA proposes that any final rule based on this proposal become effective 60 days after its date of publication in the **Federal Register**.

V. Request for Comments

Interested persons may, on or before October 2, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

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]

* * * * *

(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 (ISDEAA), 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 ISDEAA. The agenda for this meeting will consist of workgroup reports on the advantages and disadvantages of developing regulations in those subject areas provided in ISDEAA 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