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]

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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.