any SAR filed and the original of any related documentation for a period of 10 years from the date of filing the SAR. A state member bank must make all supporting documentation available to appropriate law enforcement agencies upon request. Supporting documentation shall be identified and treated as filed with the SAR.

(h) *Notification to board of directors.* The management of a state member bank shall promptly notify its board of directors, or a committee thereof, of any report filed pursuant to this section.

(i) *Compliance.* Failure to file a SAR in accordance with this section and the form's instructions may subject the state member bank, its directors, officers, employees, agents, or other institution-affiliated parties to supervisory action.

(j) *Confidentiality of SARs.* SARs are confidential. Any person subpoenaed or otherwise requested to disclose a SAR or the information contained in a SAR shall decline to produce the information citing this section, applicable law (*e.g.*, 31 U.S.C. 5318(g)), or both.

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

1. The authority citation for part 211 is revised to read as follows:

Authority: 12 U.S.C. 221 *et seq.*, 1818, 1841 *et seq.*, 1843 *et seq.*, 3100 *et seq.*, 3901 *et seq.*

§§ 211.8 and 211.24 [Amended]

2. In §§ 211.8 and 211.24(f) remove the words ''criminal referral form'' and add, in their place, the words ''suspicious activity report''.

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

1. The authority citation for 12 CFR part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1831i, 1831p-1, 1843(c)(8), 1844(b), 1972(l), 3106, 3108, 3310, 3331–3351, 3907, and 3909.

§ 225.4 [Amended]

2. In § 225.4 the heading of paragraph (f) is revised to read ''*Suspicious Activity Report.*''.

3. In § 225.4(f) remove the words ''criminal referral form'' and add, in their place, the words ''suspicious activity report''.

By order of the Board of Governors of the Federal Reserve System, June 28, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95–16250 Filed 6–30–95; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

16 CFR Part 436

Franchise Rule Review Public Workshop Conference

AGENCY: Federal Trade Commission.

ACTION: Public workshop conference

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') will hold a public workshop conference in connection with the regulatory review of the Commission's Trade Regulation Rule on Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures (''the Francise Rule'' or ''the Rule'').

DATES: The public workshop conference will be held at the Crown Sterling Suites, 7901 34th Avenue South, Bloomington, Minnesota 55425, on September 12 through 14, 1995, from 9 a.m. until 5 p.m. each day.

ADDRESSES: Notification of interest in participating in the public workshop conference should be submitted in writing on or before August 11, 1995, to Myra Howard, Division of Marketing Practices, Federal Trade Commission, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Steven Toporoff, (202) 326–3135, or Myra Howard, (202) 326–2047, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, Washington DC 20580.

SUPPLEMENTARY INFORMATION: On April 7, 1995, the Commission published a request for public comment on the Franchise Rule. 60 FR 17656 (April 7, 1995). As part of its systematic review of Commission regulations and guides, the Commission requested comments about the overall costs and benefits of the Franchise Rule and its overall regulatory and economic impact. The Commission also requested comment on whether the Rule should be modified so as to: (1) Replace the current Rule disclosure requirements with those set forth in the revised Uniform Franchise Offering Circular Guidelines, approved by the Commission on December 30, 1993; (2) modify the scope of disclosure requirements for business opportunity ventures; (3) clarify the applicability of the Rule to trade show promoters; and (4) require the disclosure of earnings information. Written comments will be accepted on or before August 11, 1995. In its request for comment on the Franchise Rule, the Commission also stated that the FTC staff would conduct a Public Workshop Conference to discuss the written comments received during the rule review.

The Public Workshop Conference will afford Commission staff and interested parties an opportunity to discuss openly issues raised during the rule review, and, in particular, to examine publicly any areas of significant controversy or divergent opinions that are raised in the written comments. Commission staff will consider the views and suggestions made during the conference, in conjunction with the written comments, in formulating its final recommendation to the Commission concerning the Franchise Rule.

The Commission staff will select a limited number of parties to represent the significant interests affected by the Franchise Rule. These parties will participate in an open discussion of the issues. It is contemplated that the selected parties might ask and answer questions based on their respective comments.

In addition, the conference will be open to the general public. Members of the general public who attend the conference may have an opportunity to make a brief oral statement presenting their views on issues raised in the rule review process. Oral statements of views by members of the general public will be limited to a few minutes. The time allotted for these statements will be determined on the basis of the time available and the number of persons who wish to make statements. The discussion will be transcribed and placed on the public record. In addition, written submissions of views, or any other written or visual materials, will be accepted during the conference and will be made part of the public record.

To the extent possible, Commission staff will select parties to represent the following affected interests: Franchisors; franchisees; business opportunity promoters; business opportunity purchasers; franchise and business opportunity trade shows organizers; franchise and business opportunity brokers; franchise consultants; economists and academicians; Federal, State and local law enforcement and regulatory authorities; and any other interests that Commission staff may identify and deem appropriate for representation.

Parties representing the above-referenced interests will be selected on the basis of the following criteria:

1. The party submits a comment during the comment period ending on August 11, 1995.

2. The party notifies Commission staff in writing of its interest and, if required, authorization to represent an affected interest, on or before August 11, 1995.

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.