Reduction Act, 44 U.S.C. 3501 *et seq.* Accordingly, repeal of the Rule would eliminate any burdens on the public imposed by these disclosure requirements.

VIII. Additional Information for Interested Persons

A. Motions or Petitions

Any motions or petitions in connection with this proceeding must be filed with the Secretary of the Commission.

B. Communications by Outside Parties to Commissioners or Their Advisors

Pursuant to Rule 1.18(c) of the Commission's Rules of Practice, 16 CFR 1.18(c), communications with respect to the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor during the course of this rulemaking shall be subject to the following treatment. Written communications, including written communications from members of Congress, shall be forwarded promptly to the Secretary for placement on the public record. Oral communications, not including oral communications from members of Congress, are permitted only when such oral communications are transcribed verbatim or summarized at the discretion of the Commissioner or Commissioner's advisor to whom such oral communications are made, and are promptly placed on the public record, together with any written communications relating to such oral communications. Memoranda prepared by a Commissioner or Commissioner's advisor setting forth the contents of any oral communications from members of Congress shall be placed promptly on the public record. If the communication with a member of Congress is transcribed verbatim or summarized, the transcript or summary will be placed promptly on the public record.

List of Subjects in 16 CFR Part 405

Advertising, Clothing, Labeling, Leather and leather products industry, Trade practices.

Authority: 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–5043 Filed 3–4–96; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860

[Docket No. 93N–0445]

Financial Disclosure by Clinical Investigators; Reopening of Comment Period and Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period and notice of meeting.

SUMMARY: The Science Board to the Food and Drug Administration (FDA), an FDA advisory committee, will hold an open committee meeting to discuss the proposed rulemaking on Financial Disclosure by Clinical Investigators, which published in the Federal Register of September 22, 1994. At the same time, FDA is reopening the comment period for the proposed rule. The proposed rule would require that the sponsor of any drug, biological product, or device submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting clinical studies to determine whether that product meets the marketing requirements specified by the agency. FDA is taking these actions in order to obtain additional comment on whether the provision on''significant payments of other sorts'' should be eliminated from the proposed rule.

DATES: The comment period is reopened until April 29, 1996. Those desiring to make formal presentations to the Science Board must notify the contact person before March 14, 1996, and submit a brief statement of the general nature of the evidence or arguments they may wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be able to be accommodated. All written statements submitted in a timely fashion will be provided to the board.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The meeting will be held at the Sheraton National Hotel, North Ballroom, 900 South Orme St. (Columbia Pike and Washington Blvd.), Arlington, VA.

FOR FURTHER INFORMATION CONTACT: Mary Gross, Office of External Affairs (HF–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3440; or the FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area) Science Board to the Food and Drug Administration, code 12603.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 22, 1994 (59 FR 48708), FDA proposed regulations to require that the sponsor of any drug, biological product, or device submit certain information concerning the compensation to, and financial interests of any clinical investigator conducting clinical studies to determine whether that product meets the marketing requirements specified by the agency. The agency is proposing to require that sponsors either certify to the absence of certain financial interests of clinical investigators or disclose those financial interests when clinical studies are submitted to FDA in support of product marketing.

FDA has asked the Science Board to discuss, at the March 29, 1996, meeting proposed § 54.4(a)(2)(ii), which would require disclosure by clinical investigators of ''significant payments of other sorts'' from sponsors. The proposed definition of such payments is ''* * * payments that exceed $5,000 (e.g., grants to fund ongoing research, compensation in the form of equipment on retainers for ongoing consultation, or honoraria) or that exceed 5 percent of the total equity in a publicly held and widely traded company.'' FDA specifically seeks discussion of the following issues:

(1) In proposing to require disclosure of any significant equity interest held by a clinical investigator in the sponsor, the agency has defined a significant equity interest as ''any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices, or any equity interest in a publicly traded corporation that exceeds 5 percent of total equity.'' Is 5 percent equity interest in a publicly traded corporation an appropriate threshold to trigger disclosure of financial information to FDA? Should a threshold dollar amount also be specified? If so, what might be a reasonable threshold amount?

(2) Are there financial arrangements that may be overlooked that could affect study outcome if FDA eliminates the provision entitled ''significant payments of other sorts,'' from the proposed rule?

(3) Does it help to narrow the scope of the provision ''significant payments of other sorts'' by raising the current payment level that would trigger

disclosure of this information from $5,000 to $50,000 annually? Are there other options that allow retention of the provision but effectively narrow its scope?

These issues will be discussed at the March 29, 1996, advisory committee meeting. Because FDA wants to provide adequate time for the submission of all relevant information related to this important public health issue, FDA is reopening the comment period.

Interested persons may, on or before April 29, 1996, submit to 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.

For further information on the administrative procedure for holding the Science Board to the Food and Drug Administration meeting and the general function of this advisory committee, see the document entitled ''Advisory Committee; notice of meeting,'' that published in the Federal Register of February 26, 1996 (61 FR 7117).

Dated: February 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–5116 Filed 3–4–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1302, 1303, 1304, 1305, 1306, 1307, 1308, 1309, 1310, 1311, 1312, 1313, and 1316

[DEA Number 139P]

RIN Number 1117–AA33

Consolidation, Elimination, and Clarification of Various Regulations

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: DEA proposes to amend the language in title 21, Code of Federal Regulations, parts 1300 through 1316. In concert with the President's National Performance Review, Regulatory Reinvention Initiative (NPR), DEA proposes to consolidate, eliminate, and clarify many of its regulations to address areas of confusion frequently raised by the pharmaceutical, chemical, and health care industries; and to correct inaccurate citations, office designations, and typographical errors.

DATES: Written comments or objections must be received by July 3, 1996.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: A comprehensive review has been conducted of title 21, Code of Federal Regulations (21 CFR), parts 1300 through 1316. Title 21 contains the rules and regulations by which DEA implements the Controlled Substances Act, the Narcotic Addict Treatment Act, the Controlled Substances Import/Export Act, the Chemical Diversion and Trafficking Act, and the Domestic Chemical Diversion Control Act. These regulations are designed to detect and deter the diversion of controlled substances and listed chemicals. DEA undertook this review to update, simplify, and consolidate its regulations in concert with the President's Regulatory Reform Initiative under the NPR; to clarify areas of confusion which have been raised by the pharmaceutical, chemical, and health care industries; and to correct inaccurate citations, office designations and typographical errors. In this effort, DEA intends to reduce some of the regulatory burden on the affected industries. The changes proposed herein build upon DEA's longstanding commitment to internal self-examination, to respond to technological advances, and to work with industry to develop the most effective and least intrusive methods of preventing and detecting the diversion of controlled substances and listed chemicals.

Among the changes being proposed, which are further described below, are the consolidation into a chart of the frequency of registration, coincident activities, and fee schedules; allowing manufacturers more latitude to set individual labeling standards; reducing the frequency of ARCOS reports from monthly to quarterly, and reducing the number of transactions to be reported by manufacturers; permitting some pharmacies to file prescriptions without marking them with a red ''C'', to transfer prescriptions for refill purposes more than once, and to retain faxed prescriptions as original documents for patients in home hospice care; and combining and streamlining various reporting, recordkeeping, and inventory requirements.

The following summarizes the changes proposed to be made to each part of the regulations:

Part 1300

DEA is proposing to move the definitions set out in 21 CFR parts 1301 through 1313 into a new part 1300. This will provide a single source for definition of the terms used in 21 CFR parts 1301 through 1313, avoiding the need for duplicate definitions in the various parts. The definitions set out in Part 1316 will remain listed in that part due to the specificity of the definitions to the subject matter of the part.

Part 1301

DEA is proposing to amend 21 CFR, part 1301 to provide a simple and clear set of requirements concerning the registration of manufacturers, distributors, dispensers, importers and exporters of controlled substances. In this regard, DEA is proposing to incorporate into 21 CFR, part 1301 the requirements relating to the registration of importers and exporters which were previously set out in 21 CFR, part 1311.

In order to provide easier reference to the primary regulations regarding registration (including separate registration for independent activities, coincident activities, the application forms and fees required for registration and reregistration, and the registration period for the various activities) DEA is proposing to amend 21 CFR, part 1301 to list such requirements in table form. Use of the table form allows for ''at-a-glance'' reference to the fundamental regulations concerning the registration requirements, rather than requiring reference to multiple pages of text in separate sections.

In addition to revising the format of 21 CFR, part 1301, DEA is proposing to transfer the definitions previously listed in § 1301.02 to the proposed new part 1300, and to remove §§ 1301.27, 1301.29, and 1301.53, relating to civil defense authorities, provisional registration of narcotic treatment programs (NTP), and waiver and modification of rules in hearings, respectively. Sections 1301.27 and 1301.29 are obsolete and § 1301.53 is duplicated by § 1316.44. With respect to civil defense authorities, DEA will continue to work with the appropriate Federal and state agencies to insure that the proper policies and procedures are in place to deal with the availability and