

to 5 p.m. and June 10, 2003, from 8:30 a.m. to 4:30 p.m.

Location: Hilton DC North—Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Joyce M. Whang, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12524. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 9, 2003, the committee will hear a presentation on post-approval studies and adverse events related to an intrapartum fetal pulse oximeter. On June 10, 2003, the committee will discuss, make recommendations, and vote on a premarket approval application for an endometrial ablation device.

Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the June 9, 2003, session will be posted on June 6, 2003. Material for the June 10, 2003, session will be posted on June 9, 2003.

Procedure: On June 9, 2003, from 2:30 p.m. to 5 p.m. and on June 10, 2003, from 8:30 a.m. to 4:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 30, 2003. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. on June 9, 2003, and between approximately 8:45 a.m. and 9:15 a.m. and 3 p.m. and 3:30 p.m. on June 10, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 30, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 9, 2003, from 12:30 p.m. to 2:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) presented by a sponsor.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 13, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03-12678 Filed 5-19-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0674]

Guidance for Industry on INDs for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "INDs for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls Information." This guidance is intended to provide recommendations to sponsors of investigational new drug applications (INDs) on the chemistry, manufacturing, and controls documentation (CMC), including microbiology documentation, that should be submitted for phase 2 and 3 studies conducted under INDs. The guidance applies to human drugs (as defined in the Federal Food, Drug, and Cosmetic Act). The guidance does not apply to botanical drug products, protein drugs derived from natural sources or produced by the use of biotechnology, or other biologics.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that

office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Charles Hoiberg, Center for Drug Evaluation and Research (HFD-800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5918.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "INDs for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls Information." The guidance is intended to: (1) Ensure that sufficient data will be submitted to the agency to assess from the CMC perspective the safety and quality of the proposed clinical studies; (2) expedite the entry of new drugs into the marketplace by clarifying the type, extent, and reporting of CMC information for phase 2 and 3 studies; and (3) facilitate drug discovery and development.

In the **Federal Register** of April 21, 1999 (64 FR 19543), FDA announced the availability of a draft version of this guidance entitled "INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format." The April 1999 guidance gave interested persons an opportunity to submit comments through July 20, 1999. All comments received during the comment period have been carefully reviewed and, where appropriate, incorporated in the guidance. The format of the guidance has been reorganized to include the relevant headings and to follow the order recommended for an application submitted in the "Common Technical Document: Quality" format (see the Quality section of the guidance entitled "M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use" that FDA announced in the **Federal Register** on October 16, 2001 (66 FR 52634)). Additional information has been included to explain the difference between CMC safety information, which should be submitted in an information amendment, and corroborating information that can be submitted in an

annual report. As a result of the public comments and editorial changes, the guidance is clearer and more concise than the draft version. Furthermore, the scope of the guidance has been changed to exclude proteins and biologics. The agency is considering developing a separate guidance on INDs for these types of drugs.

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB Control No. 0910–0014.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on CMC content and format of INDs for phase 2 and 3 studies of certain drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 13, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12545 Filed 5–19–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects (section 3506 (c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Ryan White Comprehensive AIDS Resources Emergency (CARE) Act and Minority AIDS Initiative (MAI) Survey: New

The purpose of the Ryan White CARE Act is to provide emergency assistance to localities that are disproportionately affected by the human immunodeficiency virus (HIV) epidemic and to make financial assistance available for the development, organization, coordination, and operation of more effective and cost-efficient systems for the delivery of essential services to persons with HIV disease. The CARE Act also provides grants to States, eligible metropolitan areas, community-based programs, and early intervention programs for the delivery of services to individuals and families with HIV infection.

The HRSA's HIV/AIDS Bureau (HAB) administers Titles I, II, III, and IV of the Ryan White CARE Act of 1990, as amended by the Ryan White CARE Act

Amendments of 1996 and 2000 (codified under Title XXVI of the Public Health Service Act).

In 1998, President Clinton declared that HIV was a severe and ongoing health crisis among racial/ethnic minority communities. In response to the President's declaration, in fiscal year 1999 the Congressional Black Caucus (CBC) announced funding of a new initiative to address the disproportionate impact of HIV on African-American and Hispanic communities. Since 1999, the initial CBC initiative has been broadened to address the HIV epidemic in other racial and ethnic minority communities. Currently, the HRSA, the Centers for Disease Control and Prevention, the National Institutes of Health, the Office of Public Health and Sciences' Office of Minority Health, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration allocate MAI funds. Direct service providers receiving MAI funds through HAB include organizations whose board of directors and/or direct service employees are racial/ethnic minorities, as well as organizations whose mission is focused on providing care to racial/ethnic minority populations.

The Fax Consultation Form for Minority Providers and Providers Receiving MAI Funds is designed to collect information from (1) service providers receiving MAI funds and (2) service providers funded by the Ryan White CARE Act whose board members or direct service staff are predominantly racial/ethnic minority members.

The Fax Consultation Form will address several over-arching questions including: (1) Have the MAI funds increased the number of persons served and the type and availability of services provided in communities of color; (2) have the MAI funds increased the capacity of minority and other CARE Act service providers to provide care and services in communities of color; (3) what has been the impact of MAI funded training, technical assistance (TA), and capacity building of minority and other organizations; and (4) what administrative impact have MAI funds had on CARE Act programs? Information obtained from the Fax Consultation Form for Minority Providers and Providers Receiving MAI Funds will be used to address the over-arching questions, plan new technical assistance and capacity development activities, and inform HAB policies and program management.

The Fax Consultation Form for Minority Providers and Providers Receiving MAI Funds will be transmitted by facsimile to service