

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.

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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