Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,189 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 15, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 12, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 13, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–3781 Filed 3–16–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of the Committee: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 27, 2006, from 10 a.m. to 5:45 p.m., and on March 28, 2006, from 8 a.m. to 3 p.m.

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

Contact: Michael Bailey, 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 3014512524. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 27, 2006, the committee will discuss, make recommendations, and vote on a premarket approval application for a post-surgical adhesion prevention device for use in patients undergoing gynecological laparoscopic surgical procedures. On March 28, 2006, the committee will have a general topic discussion of clinical trial design issues for new devices intended to treat symptomatic uterine fibroids. 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*.

Procedure: On March 27, 2006, from 10 a.m. to 5:45 p.m., and on March 28, 2006, from 9 a.m. to 3 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 March 20, 2006. Oral presentations from the public will be scheduled on March 27, 2006, between approximately 10:10 a.m. and 10:40 a.m. and between approximately 4:15 p.m. and 4:45 p.m., and on March 28, 2006, between approximately 10:15 a.m. and 11:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 20, 2006, 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 March 28, 2006, from 8 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) regarding pending and future device issues.

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 240–276–0450, ext. 113, at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: March 7, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–3786 Filed 3–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0103]

Guidance for Industry on Using a Centralized IRB Process in Multicenter Clinical Trials; 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 ''Using a Centralized IRB Process in Multicenter Clinical Trials.'' The guidance is intended to assist sponsors, institutions, institutional review boards (IRBs), and clinical investigators involved in multicenter clinical research in meeting the requirements of FDA regulations by

facilitating the use of a centralized IRB review process.

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

ADDRESSES: Submit written requests for single copies of the 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, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Nancy Stanisic, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1660, or

Steve Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration,1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210, or

David Lepay, Good Clinical Practice Program, Office of Science and Health Coordination (HF–34), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 28, 2005 (70 FR 15635), FDA published a notice announcing the availability of a draft guidance entitled ''Using a Centralized IRB Process in Multicenter Clinical Trials.'' The notice gave interested persons an opportunity to submit comments by May 27, 2005. The agency received only a small number of comments, and we carefully considered the received comments as we finalized the draft guidance. Other than minor editorial changes and some clarifications, no substantive changes were made to the draft guidance.

This guidance is intended to assist sponsors, institutions, IRBs, and clinical investigators involved in multicenter clinical research in meeting the requirements of 21 CFR part 56 by facilitating the use of a centralized IRB review process. The guidance does the following: (1) Describes the roles of the participants in a centralized IRB review process, (2) offers guidance on how a centralized IRB review process might consider the concerns and attitudes of the various communities participating in a multicenter clinical trial, (3) makes recommendations about documenting agreements between a central IRB and the IRBs at institutions involved in the centralized IRB review process concerning the responsibilities of a central IRB and each institution's IRB, and (4) discusses IRB procedures for implementing a centralized review process. Finally, the guidance recommends how to ensure effective IRB review for clinical trial sites not already affiliated with an IRB. This guidance applies to clinical investigations conducted under 21 CFR part 312 (investigational new drug application or IND regulations).

This level 1 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 this topic. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper copies, 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 are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/cder/guidance/index.htm*. *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3785 Filed 3–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–06–8000]

Confidentiality Arrangement Between the United States Food and Drug Administration and the French Health Products Safety Agency

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a confidentiality arrangement between the United States Food and Drug Administration and the French Health Products Safety Agency. The purpose of this confidentiality arrangement is to establish mutual commitments to retain the confidentiality of non-public information shared between the agencies.

DATES: The agreement became effective February 8, 2006.

FOR FURTHER INFORMATION CONTACT: Matthew E. Eckel, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville MD, 20857, 301–827–4480, FAX: 301–480–0716.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and understandings between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this confidentiality arrangement.

Dated: March 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S