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