common application form is intended to complement, not to supersede, the relevant regulatory frameworks currently in effect. The sponsor must comply with all applicable regulatory requirements in each jurisdiction in which it seeks designation when using this common application form.

To use the common application form, the sponsor must provide the required information in each applicable section as instructed in the explanatory notes. Certain information elements are identified in the form as required exclusively by either FDA or EMEA regulations, and as such they must be included only in the application to that jurisdiction. Where additional explanations and/or supportive documents are necessary, the sponsor should sequentially append them at the end of the common application form in the order they appear in the form. The sponsor must also complete the declaration and signature page. For FDA, the completed common application form and required appended documents must be submitted to the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. For EMEA, the completed documents must be submitted to European Medicines Agency, 7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom.

FDA estimates the reporting burden of this common application form as follows. Between January 2000 and May 2006, FDA and EMEA received 226 comparable orphan designation requests/applications of the same drugs for the same diseases or conditions, or an average of 35 per year. With the ease of a common application form, FDA anticipates the number of such requests/applications may increase over time. Therefore, generally there is one request/application per respondent and as, at the extreme, all respondent are U.S.-based, FDA believes up to 40 such respondents may use the common application form each year. The respondents will be primarily pharmaceutical companies or other for-profit organizations. The collection of information for sponsors requesting orphan drug designation from FDA is currently covered by the Orphan Drug Regulations (21 CFR Part 316) and approved under OMB No. 0910–0167 (expires August 31, 2010). For applications submitted exclusively to FDA, we do not believe the new form will result in any increased burden on the respondents and therefore we estimate no additional burden for those respondents. FDA believes the information required for the EMEA submission, for the most part, is very similar to that in the FDA submission, which is already in the respondents' possession. The respondents, however, may have to search existing data sources or gather additional needed data, such as on the prevalence or the availability of alternative methods of diagnosis, prevention, and treatment of the rare disease or condition of interest in the European Community, to complete the EMEA submission. FDA estimates that it will take an additional 32 hours (16 hours of professional time and 16 hours of support time) to compile information required for the EMEA submission. Hence, the estimated total annual human resource hours, at most, would be 1,280 hours.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	Annual No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3671	40	1	40	32	1,280

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21988 Filed 11–8–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007M–0366]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Summaries of Safety and Effectiveness Data for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability through the Internet and FDA's Division of Dockets Management of summaries of safety and effectiveness data of approved PMAs.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness data.

FOR FURTHER INFORMATION CONTACT: Pamela Pope, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at *http://www.fda.gov*. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act.

The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness data were placed on the Internet from July 1, 2007, through September 30, 2007. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1. LIST OF SUMMARIES OF SAFETY AND EFFECTIVENESS DATA FOR APPROVED PMAS MADE AVAILABLE JULY 1, 2007, THROUGH SEPTEMBER 30, 2007.

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP060001/0/2007M–0366	ThermoGenesis Corp.	CryoSeal FS System	7/26/2007

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cber/products.htm*.

Dated: October 31, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21986 Filed 11–8–07; 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 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 December 13, 2007, from 8 a.m. to 5 p.m., and on December 14, 2007, from 8 a.m. to 1:15 p.m.

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

Contact Person: Michael Bailey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4100, 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. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 13, 2007, the committee will discuss, make recommendations, and vote on a premarket approval application for the Adiana Transcervical Sterilization System, sponsored by Cytyc Surgical Products. This device is indicated to be used as a permanent method for female sterilization. On December 14, 2007, the committee will have a general topic discussion of clinical trial design issues for endometrial ablation devices indicated for pre-menopausal women in whom childbearing is complete and who no longer desire menses (i.e., monthly period). The committee will also hear and discuss a post-approval study update for the ExAblate 2000 System from InSightec, Inc. The system is indicated for ablation of uterine fibroid tissue in pre- or peri-menopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: On December 13, 2007, from 8 a.m. to 5 p.m., and on December 14, 2007, from 9 a.m. to 1:15 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 on or before November 29, 2007. Oral presentations from the public will be scheduled on December 13, 2007, between approximately 8:15 a.m. and 8:45 a.m. and between approximately 3:30 p.m. and 4 p.m., and on December 14, 2007, between approximately 10 a.m. and 10:15 a.m. and between approximately 11:15 a.m. and 12:15 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before November 21, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 23, 2007.

Closed Presentation of Data: On December 14, 2007, 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)). The committee will hear an update on device submissions currently under review.

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