

223 postmarketing studies and would be required to submit an annual progress report on those postmarketing studies under § 601.70. Based on past experience with similar reporting requirements, the agency estimates that

it takes an applicant approximately 24 hours (8 hours per study x 3) annually to gather, complete, and submit the appropriate information for each report (approximately two to four studies per report). Included in these 24 hours is

the time necessary to prepare and submit two copies of the annual progress report of postmarketing studies to FDA under § 601.70(d).

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.70(b) and (d)	44	1.5	65	24	1,560

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

Dated: June 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery 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: General and Plastic Surgery 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 July 24, 2003, from 8 a.m. to 5 p.m.

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

Contact Person: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12519. Please call the Information Line or access the “CDRH Advisory Committees” Web page at <http://www.fda.gov/cdrh/panelmtg.html> for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on the reclassification of a transitional class III device, the absorbable hemostatic agent and dressing device intended for hemostasis during surgical procedures. There will also be a discussion of clinical trial issues for devices designed for percutaneous removal of breast tumors. Background information for each topic, 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 July 24, 2003, from 8:30 a.m. to 5 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 July 10, 2003. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 8:45 a.m., 11 a.m. and 11:15 a.m., and 1:15 p.m. and 1:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 10, 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 July 24, 2003, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) relating to pending issues and applications.

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: June 19, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–16112 Filed 6–25–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug and Biological Product Consolidation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is transferring certain product oversight responsibilities from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This consolidation initiative provides the opportunity to further develop and coordinate scientific and regulatory activities between CBER and CDER. FDA believes that as more drug and biological products are developed for a broader range of illnesses, such interaction is necessary for both efficient and consistent agency action.

FOR FURTHER INFORMATION CONTACT:

Deborah J. Henderson, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5406,