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 BURDEN[1]

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.

[FR Doc. 03–16160 Filed 6–25–03; 8:45 am]

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]

BILLING CODE 4160–01–S

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,

or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–25), 1401 Rockville Pike, suite 200 N., Rockville, MD 20852, 301–827–0372.

SUPPLEMENTARY INFORMATION:

I. The Consolidation Initiative

A. Therapeutic Biological Products Transferred to CDER

As of June 30, 2003, responsibility for regulating most therapeutic biologics, with certain exceptions (e.g., cell and gene therapy products and therapeutic vaccines) will be transferred from the Office of Therapeutics Research and Review (OTRR), CBER, to the Office of New Drugs (OND), and the Office of Pharmaceutical Science (OPS), CDER. Initially, this transfer of products will take place as the divisions of OTRR within CBER are detailed to offices within CDER. As of June 30, 2003:

- The Division of Therapeutic Proteins and the Division of Monoclonal Antibodies of OTRR, CBER, will be detailed to OPS, CDER.
- The Division of Clinical Trial Design and Analysis, the Division of Application Review and Policy, and the immediate office of the Director, OTRR, CBER, will be detailed to OND, CDER.

FDA anticipates that as of the start of fiscal year 2004 on October 1, 2003, the offices detailed to CDER will be incorporated into CDER's organizational structure, including the creation of a new Office of Drug Evaluation (ODE) in OND, CDER.

B. Therapeutic Biological Products Remaining in CBER

Under a previous reorganization, cell and gene therapy products from the Division of Cellular and Gene Therapies, OTRR, CBER were transferred to a new office, the Office of Cellular, Tissue and Gene Therapies (OCTGT).

Overall responsibility for therapeutic vaccines will remain in CBER. The clinical review of therapeutic vaccine-associated investigational new drug applications (INDs) and biologics license applications (BLAs) will be conducted by CBER and coordinated with the consolidated clinical expertise area in CDER.

II. Web Site Listing CBER Applications Transferred to CDER and Contact Information

FDA has created a Web site listing the identification numbers of the INDs, BLAs, investigational device exemptions, and new drug applications in CBER that are being transferred to CDER. Holders of all CBER applications are encouraged to check this Web site to determine which, if any, of their applications are being transferred and to find new contact information. The Web site address is: *http://www.fda.gov/cber/transfer/transfer.htm*. Until notified by CDER, submitters should continue to send submissions to the CBER Document Control Center.

III. Delegations of Authority

As a result of this product consolidation and the resulting changes to the organizational structure of CDER and CBER, the agency has conducted a comprehensive update of the delegations of authority to reflect organizational changes. Current program delegations of authority for CDER and CBER have been revised to reflect these changes. Delegations of authority give particular officials in the Centers the legal authority needed to take substantive actions and perform certain functions of the Commissioner of Food and Drugs. These changes will be made to the agency's Staff Manual Guide (SMG) system available on the Internet at *http://www.fda.gov/smg*. While comprehensive changes have been made to the delegations, the agency believes the current delegation at SMG 1410.702 provides CDER with all necessary authority for the premarket approval of any biological product for which CDER has oversight. Furthermore, revised SMG 1410.202 provides CDER with the necessary authority to perform all functions of the Director of CBER with respect to biological products transferred to CDER.

IV. Regulations Affected by the Product Consolidation

The agency is in the process of making technical amendments to its regulations affected by this reorganization and anticipates these revisions will be completed by the beginning of fiscal year 2004 on October 1, 2003, or shortly thereafter. Any revisions to FDA's regulations will be published in the **Federal Register** upon completion.

Dated: June 20, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16242 Filed 6–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0281]

Medical Devices: A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Final Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of final guidance entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff.'' This guidance is intended to assist the medical device industry and FDA staff in implementing a voluntary pilot premarket review program that may reduce the burden on manufacturers who face conflicting premarket submission format and content requirements in different countries. The proposed pilot program will evaluate the utility of an alternative submission procedure as described in the document entitled ''Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices,'' otherwise known as the ''draft STED document.'' The draft STED document was developed by Study Group 1 (SG1) of the Global Harmonization Task Force (GHTF), and issued as a working draft in December 2000. The GHTF is a voluntary group comprised of medical device regulatory officials and industry representatives from the United States, Canada, Australia, the European Union, and Japan. Each of these member countries will participate in the pilot program and will provide specific directions for implementing the program within their respective jurisdictions. This guidance takes effect upon the date of its publication.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-