burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting (OMB Control Number 0910–0437)—Extension

Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(a),(b), and (c)) requires user facilities, manufacturers, and importers of medical devices to report adverse events involving medical devices to FDA. On December 11, 1995 (60 FR 63597), FDA issued part 803 (21 CFR part 803) that implemented section 519 of the act. The regulation was amended to conform with the changes reflected in the 1997 FDA Modernization Act.

Information from these reports will be used to evaluate risks associated with medical devices and to enable FDA to take appropriate regulatory measures to protect the public health.

Respondents to this collection of information are businesses or other for profit and non-profit organizations including user facilities, manufacturers, and importers of medical devices.

FDA estimates the burden of this collection 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
803.19	25	1	25	3	75
803.30	1,000	3	3,000	1	3,000
803.33 FDA Form 3419	1,000	1	1,000	1	1,000
803.40	50	10	500	1	500
803.50	1,500	34	51,000	1	51,000
803.55 FDA Form 3417	700	5	3,500	1	3,500
TOTALS					59,075

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.17	3,200	1	3,200	3.3	10,560
803.18[2]	39,000	1	39,000	1.5	58,500
TOTAL					69,060

[1] There are no capitol costs or operating and maintenance costs associated with this collection of information.
[2] Include an estimated 35,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints.

The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the MDR requirements as part of their internal quality control system.

Part 803 requires user facilities to report incidents where a medical device caused or contributed to a death or serious injury to the device manufacturer and to FDA (in case of death). Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way that should the malfunction recur, it would be likely to cause or contribute to death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown. If the manufacturer is unknown, the importer sends the reports to FDA.

The agency has estimated that on average, 1,800 entities annually would be required to establish new procedures or revise existing procedures in order to comply with medical device report (MDR) provisions. For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers which are not required to revise their written procedures to comply with this provision are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Dated: September 24, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–24811 Filed 9–30–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; 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). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

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

Dates and Time: The meeting will be held on October 21, 2002, from 8:30 a.m. to 5 p.m. and October 22, 2002, from 8:30 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee conference rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Kathleen Reedy, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, or e-mail: REEDYK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 21, 2002, the committee will: (1) Receive summary reports and provide direction for the Nonclinical Studies Subcommittee and the Process Analytical Technologies Subcommittee; (2) receive updates on risk-based chemistry manufacturing control review and blend uniformity; and (3) discuss and provide comments on regulatory issues related to crystal habits—polymorphism. On October 22, 2002, the committee will: (1) Discuss and provide direction for future subcommittee—Good Manufacturing Practices/Manufacturing Subcommittee; and (2) discuss manufacturing issues; sterile drug products produced by aseptic processing.

Procedure: 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 October 14, 2002. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:45 p.m. on October 21, 2002, and 1 p.m. and 2 p.m. on October 22, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 14, 2002, 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.

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 Kathleen Reedy 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: September 22, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–24812 Filed 9–30–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science; 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). The meeting will be open to the public.

Name of Committee: Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science.

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 October 23, 2002, from 8:30 a.m. to 5 p.m.

Location: Ramada Inn, Georgetown and Montrose Conference Rooms, 1775 Rockville Pike, Rockville, MD.

Contact Person: Kathleen Reedy, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: REEDYK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss: (1) Computer systems validation—21 CFR part 11 issues pertinent to process analytical technologies (PAT), (2) a PAT case study, and (3) rapid microbiology testing.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 14, 2002. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 14, 2002, 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.

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 Kathleen Reedy 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: September 22, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–24813 Filed 9–30–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

RIN 1018–AI55

Fiscal Year (FY) 2002 Landowner Incentive Program (Non Tribal Portion) for States, Territories and the District of Columbia; Final Policy With Implementation Guidelines, and Request for Proposals

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final policy with implementation guidelines; notice of request for proposals.

SUMMARY: The Department of the Interior and Related Agencies Appropriations Act 2002 allocated $40 million from the Land and Water Conservation Fund for conservation grants to States, the District of Columbia, Puerto Rico, Guam, the United States Virgin Islands, the Northern Mariana Islands, and American Samoa (hereafter referred to collectively as States), and Tribes under a Landowner Incentive Program (LIP).