Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rules are necessary, to select regulatory approaches that maximize net benefits (including potential economic environments, public health and safety, other advantages, distributive impacts, and equity). We believe that this notice is consistent with the regulatory philosophy and principles identified in the Executive Order. The formula for the allotments is specified in the statute. Since the formula is specified in the statute, we have no discretion in determining the allotments. This notice merely announces the results of our application of this formula, and therefore does not reach the economic significance threshold of $100 million in any 1 year.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 to $29 million in any one year. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before publishing any notice that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $110 million or more (adjusted each year for inflation) in any 1 year. Because participation in the SCHIP program on the part of States is voluntary, any payments and expenditures States make or incur on behalf of the program that are not reimbursed by the Federal government are made voluntarily. This notice will not create an unfunded mandate on States, tribal, or local governments because it merely notifies States of their SCHIP allotment for FY 2003. Therefore, we are not required to perform an assessment of the costs and benefits of this notice.

Low-income children will benefit from payments under SCHIP through increased opportunities for health insurance coverage. We believe this notice will have an overall positive impact by informing States, the District of Columbia, and U.S. Territories and Commonwealths of the extent to which they are permitted to expend funds under their child health plans using their FY 2003 allotments.

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism. We have reviewed this notice and determined that it does not significantly affect States' rights, roles, and responsibilities because it does not set forth any new policies.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this notice will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Section 1102 of the Social Security Act (42 U.S.C. 1302))

(Catalog of Federal Domestic Assistance Program No. 93.767, State Children's Health Insurance Program)

Dated: August 6, 2002.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: August 23, 2002.

**Tommy G. Thompson,**

*Secretary of Health and Human Services.*

[FR Doc. 02–24846 Filed 9–27–02; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0405]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for medical device reporting: Manufacturer reporting, importer reporting, user Facility reporting, and distributor reporting.

**DATES:** Submit written or electronic comments on the collection of information by December 2, 2002.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the

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.