Respondents: 5,000; *Total Annual Responses:* 5,000; *Total Annual Hours:* 417.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conflict of Interest and Ownership and Control Information; *Form No.:* CMS–R–312 (OMB# 0938–0795); *Use:* This information is required by Public Law 95–142 as a condition of participation in the Medicare program. The Fiscal Intermediaries and Carriers are contractually required as a condition for renewal of their contracts to submit to CMS any ownership and control interest information; *Frequency:* Annually; *Affected Public:* Not-for-profit institutions and business or other for-profit; *Number of Respondents:* 37; *Total Annual Responses:* 37; *Total Annual Hours:* 11,100.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 29, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–10388 Filed 5–6–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–53, CMS–R–118 and CMS–10107]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Imposition of Cost Sharing Charges Under Medicaid and Supporting Regulations contained in 42 CFR 447.53; *Form No.:* CMS–R–53 (OMB# 0938–0429); *Use:* The information collection requirements contained in 42 CFR 447.53 require the States to include in their Medicaid State Plan their cost sharing provisions for the medically and categorically needy. The State Plan is the method in which States inform staff of State policies, standards, procedures and instructions; *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 52; *Total Annual Responses:* 2; *Total Annual Hours:* 20.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Quality Improvement (formerly Peer Review) Organization Contracts: Solicitation of Statements of Interest from In-State Organizations, General Notice and Supporting Regulations in 42 CFR 475.102, 475.103, 475.104, 475.105 and 475.106; *Form No.:* CMS–R–118 (OMB# 0938–0526); Use: This notice is a solicitation of sources for the procurement of medical review services. The information is required for potential contractors to demonstrate that they meet the statutory requirements as Peer Review Organizations (also known as Quality Improvement Organizations). Compliance with these requirements is voluntary; *Frequency:* Other: As needed, not recurring; *Affected Public:* Business or other for-profit; *Number of Respondents:* 53; *Total Annual Responses:* 53; *Total Annual Hours:* 1.

3. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Instrument/Tool for Refinement of a Prospective Payment System for Patints in Inpatient Psychiatric Hospitals, and units: a pilot test; *Form No.:* CMS–10107 (OMB# 0938–NEW); *Use:* This is a request to pilot test an instrument to refine the PPS for inpatient psychiatric facilities. This testing will include assessing the feasibility of administering this instrument, and testing the reliability, validity, time and process of administration.; *Frequency:* Other: per stay per diem; *Affected Public:* Business or other for-profit, not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 1,120; *Total Annual Responses:* 1,120; *Total Annual Hours:* 2,464.

4. *Type of Information Request:* New Collection; *Title of Information Collection:* Evaluation of PACE as a Permanent Program and a For-Profit Demonstration; *Form No.:* CMS–10103 (OMB #0938–NEW); *Use:* The Balanced Budget Act of 1997 (BBA) established PACE as a permanent Medicare program and a state option under Medicaid. It also mandated a for-profit demonstration and a study of the ''quality and cost'' of the permanent program ''under the Medicare and Medicaid programs.'' All PACE Demonstration sites must convert to permament program sites in 2003. This evaluation will build on the efforts made in the first PACE evaluation (final reports in 2000). Data will be gathered to assess changes in access to care, patient satisfaction, mortality, organizational/operational changes, patient characteristics, outcomes, quality, etc. that have resulted from the BBA legislation. Patient surveys, site syrveys, and claims and utilization data gathered at 12 sites will help answer these study questions. Mathematics Policy Research, Inc. is awarded a contract (No. 500–00–0033) to perform this evaluation. A final report is expected in the summer of 2006;

Frequency: Other: One-time; *Affected Public:* Individuals or households, not-for-profit institutions; *Number of Respondents:* 2,753; *Total Annual Responses:* 2,753; *Total Annual Hours:* 1,330.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov*, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 29, 2004.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 04–10389 Filed 5–6–04; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2003M–0337, 2003M–0332, 2003M–0343, 2003M–0242, 2003M–0333, 2003M–0339, 2003M–0320, 2003M–0356, 2003M–0305, 2003M–0352, 2003M–0381, 2003M–0375, 2003M–0427]

Medical Devices; Availability of Safety and Effectiveness Summaries 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. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite 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.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

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**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. 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 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 regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2003, through September 30, 2003. 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 SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2003, THROUGH SEPTEMBER 30, 2003

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P000013/2003M–0337	Howmedica Ostenonics Corp.	OSTEONICS ABC SYSTEM & TRIDENT SYSTEM HIP PROSTHESIS	February 3, 2003
P010001/2003M–0332	Ceramtec AgWright Medical Technology	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	February 3, 2003
P020052/2003M–0343	St. Jude Medical, Daig Division, Inc.	RESPONSE CV CATHETER SYSTEM	May 7, 2003