Medicaid Statement of Expenditures for the Medical Assistance Program; *Use:* The State Medicaid Agencies use the form CMS–64 to report their actual program benefit costs and administrative expenses to CMS. CMS uses this information to compute the Federal financial participation for the State's Medicaid Program costs. *Form Number:* CMS–64 (OMB# 0938–0067); *Frequency:* Quarterly; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 18,144.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Quarterly Children's Health Insurance Program Statement of Expenditures for Title XXI; *Use:* States use the form CMS–21 to report budget, expenditure, and related statistical information required for implementation of the Children's Health Insurance Program. *Form Number:* CMS–21 and 21B (OMB# 0938–0731); *Frequency:* Quarterly; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 448; *Total Annual Hours:* 7,840.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The Fiscal Soundness Reporting Requirements; *Use:* CMS is assigned responsibility for overseeing all Medicare Advantage Organizations (MAO) on-going financial performance. CMS needs the requested collection of information to establish that each MAO maintains a fiscally sound organization. *Form Number:* CMS–906 (OMB# 0938–0469); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 700; *Total Annual Responses:* 700; *Total Annual Hours:* 233.

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://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *June 2, 2008:*

1. *Electronically*. You may submit your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail*. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 27, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–6771 Filed 4–1–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–148, CMS–R–185, CMS–R–50, CMS–10112 and CMS–287–05]

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

AGENCY: Centers for Medicare & 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 & Medicaid Services (CMS), 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 function; (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 without change of a currently approved collection; *Title of Information Collection:* Limitations on Provider Related Donations and Health Care Related Taxes; Limitation on Payments for Disproportionate Share Hospitals and Supporting Regulations in 42 CFR 433.68, 433.74 and 447.272; *Use:* This information collection is necessary to ensure compliance with Sections 1903 and 1923 of the Social Security Act for the purpose of preventing payments of Federal financial participation on amounts prohibited by statute. *Form Number:* CMS–R–148 (OMB# 0938–0618); *Frequency:* Quarterly and occasionally; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 40; *Total Annual Hours:* 3,200.

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of State Exemption Under State Laboratory Programs and Supporting Regulations in 42 CFR 493.551–493.557. *Form Number:* CMS–R–185 (OMB# 0938–0686); *Frequency:* On occasion; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 8; *Total Annual Responses:* 96; *Total Annual Hours:* 384.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medical Records Review under the Prospective Payment System (PPS) and Supporting Regulations in 42 CFR 412.40–412.52; *Use:* The Social Security Amendments of 1983 (Public Law 98–21), requires quality improvement organization (QIO) review of medical services provided to Medicare beneficiaries. Review of services under the QIO program can be accomplished by individual case review and the Clinical Data Abstraction Centers (CDACs). Accordingly, QIOs must review, at the direction of CMS: (1) All anti-dumping referrals; (2) beneficiary complaints involving quality issues; (3) potential gross and flagrant violations of unnecessary admission concerns identified during project data collection; (4) requests from hospitals for higher-weighted DRG adjustments; (5) hospital and managed care plan issued notices of non-coverage; (6) specific codes for assistants at cataract surgery; and (7) cases referred by CMS, the Office of the Inspector General, the Department of Justice, the managed care appeals contractor, intermediaries, carriers, or the CDACs. *Form Number:* CMS–R–50 (OMB# 0938–0359);

Frequency: Yearly; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 6,100; *Total Annual Responses:* 276,500; *Total Annual Hours:* 8,280.

4. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Phone Surveys of Products and Services for Medicare Payment Validation and Supporting Regulations in 42 CFR 405.502. *Use:* The phone surveys of products and services for Medicare payment validation and supporting regulations in 42 CFR 405.502 will be used to identify specific products/services provided to Medicare beneficiaries and the costs associated with the provision of those products/services. The information collected will be used to validate the Medicare payment amounts for those products/services and institute revisions of payment amounts where necessary. The respondents will be the companies that have provided the product/service under review to Medicare beneficiaries. *Form Number:* CMS–10112 (OMB# 0938–0939); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 4,000; *Total Annual Responses:* 4,000; *Total Annual Hours:* 16,000.

5. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Chain Home Office Cost Statement and supporting Regulations in 42 CFR 413.17 and 413.20; *Use:* The Form CMS–287–05 is filed annually by Chain Home Offices to report the information necessary for the determination of Medicare reimbursement to components of chain organizations. However, where providers are components of chain organizations, information included in the chain home office cost statement is in addition to that included in the provider cost report and is needed to determine whether payments are appropriate. *Form Number:* CMS–287–05 (OMB# 0938–0202); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,345; *Total Annual Responses:* 1,345; *Total Annual Hours:* 626,770.

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://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *May 2, 2008.* OMB Human Resources and Housing Branch, Attention: Carolyn Raffaelli, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: March 27, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–6773 Filed 4–1–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0203] (formerly Docket No. 2003E–0402)

Determination of Regulatory Review Period for Purposes of Patent Extension; ACRYSOF

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ACRYSOF and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman,Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA approved for marketing the medical device ACRYSOF. ACRYSOF is indicated for replacement of the human lens to achieve visual correction of aphakia in adults when extracapsular cataract extraction or phacoemulsification are performed. These lenses are intended for placement in the capsular bag. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ACRYSOF (U.S. Patent No. 5,470,932) from Alcon Manufacturing, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 6, 2004, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of ACRYSOF represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ACRYSOF is 1,084 days. Of this time, 538 days occurred during the testing phase of the regulatory review period, while 546 days occurred during the approval phase. These periods of time were derived from the following dates: