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:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: July 7, 2000. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective on June 8, 2000. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on July 7, 2000, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: December 26, 2001. The applicant claims December 21, 2001, as the date the premarket approval application (PMA) for ACRYSOF (PMA P930014/S009) was initially submitted. However, FDA records indicate that PMA P930014/S009 was submitted on December 26, 2001.

3. *The date the application was approved*: June 24, 2003. FDA has verified the applicant's claim that PMA P930014/S009 was approved on June 24, 2003.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 832 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 2, 2008. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 29, 2008. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 16, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E8–6851 Filed 4–1–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0184]

Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications

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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing temporary marketing permit applications.

DATES: Submit written or electronic comments on the collection of information by June 2, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Jonna Capezzuto,Office of the Chief Information Officer (HFA–250), Food and Drug Administration,5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 these topics: (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.

Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i) (OMB Control Number 0910–0133)—Extension

Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food ''[w]henever * * * such action will promote honesty and fair dealing in the interest of consumers * * * .'' Under section 403(g) of the act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) enables the agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable