DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 27, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–5978 Filed 7–3–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: OCSE–75 Tribal Child Support Enforcement Program Annual Data Report.

OMB No.: New Collection.

Description: The data collected by form OCSE–75 are used to prepare the OCSE preliminary and annual data reports. In addition, Tribes administering CSE programs under Title IV–D of the Social Security Act are required to report program status and accomplishments and submit the OCSE–75 report annually.

Respondents: Tribal Child Support Enforcement Organizations or the Department/Agency/Bureau responsible for Child Support Enforcement in each Tribe.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–75	9	1	2.5	22.5

Estimated Total Annual Burden Hours: 22.5.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollectionrsargis@acf.hhs.gov.* All requests should be sent to *infocollection@acf.hhs.gov* identifying the request by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 27, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–5979 Filed 7–3–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: 45 CFR Part 1303—Appeal Procedures for Head Start and Early Head Start Grantees and Current or Prospective Delegate Agencies.

OMB No.: 0980–0242.

Description: Section 646 of the Head Start Act requires the Secretary of Health and Human Services to prescribe a timeline for conducting administrative hearings when adverse actions are taken or proposed against Head Start and Early Head Start grantees and delegate agencies. The Office of Head Start is proposing to renew, without changes, this rule, which implements these requirements and which prescribes when a grantee must submit certain information and what that information shall include.

Respondents: Head Start and Early Head Start grantees and Delegate Agencies.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Rule	20	1	26	520

Estimated Total Annual Burden Hours: 520.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF. E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: June 26, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–5980 Filed 7–3–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0396]

Determination of Regulatory Review Period for Purposes of Patent Extension; TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System 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.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 recently approved for marketing the medical device TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System. TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of *de novo* lesions ≤28 mm in length in native coronary arteries ≥2.5 to ≤3.75 mm in diameter. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System (U.S. Patent No. 5,716,981) from Angiotech Phamaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 24, 2006, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System 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 TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System is 716 days. Of this time, 456 days occurred during the testing phase of the regulatory review period, while 260 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 involving this device became effective*: March 21, 2002. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective on October 25, 2001. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on March 21, 2002, which represents the IDE effective date.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: June 19, 2003. The applicant claims February 25, 2003, as the date the premarket approval application (PMA) for TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System (PMA P030025) was initially submitted. However, FDA records indicate that PMA P030025 was submitted in modules and was not substantially complete until the final submission of clinical data on June 19, 2003.

3. *The date the application was approved*: March 4, 2004. FDA has verified the applicant's claim that PMA P030025 was approved on March 4, 2004.

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 807 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may