States have been required to report on at least one of the quality elements for a portion of the provider population. ACF is proposing that, effective with the October 2017 report, States must report quality information for every child care provider. States with a QRIS, at a minimum, would be required to report QRIS participation and rating for every provider. States without QRIS would be required to report quality information for every provider using one or more of the quality elements on the form. ACF is proposing to add a new option to indicate whether or not the provider is subject to Head Start or Early Head Start standards.

- *Inspection Date:* Section 658E(c)(2)(J) of the reauthorized CCDBG Act requires States to monitor both licensed and license-exempt CCDF providers. ACF proposes to add a data element effective October 2017 indicating, for each child care provider delivering services to a CCDF child, the date of the most recent inspection for compliance with health, safety, and fire standards (including licensing standards for licensed providers).
- *Personally Identifiable Information:* Section 658K(a)(1)(E) of the CCDBG Act now prohibits the ACF–801 report from containing personally identifiable information. As a result, ACF proposes to delete Social Security Numbers (SSNs) from the report. Note that the form will still require a unique identifying number, other than the SSN, that is assigned by the State for each family.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Mariana Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–801	56	4	25	5,600

Estimated Total Annual Burden Hours: 5,600.

In compliance with the requirements of Section 506(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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–10988 Filed 5–6–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Care and Development Fund Annual Aggregate Report—ACF–800.

OMB No.: 0970–0150.

Description: Section 658K of the Child Care and Development Block Grant (CCDBG) Act (42 U.S.C. 9858, as amended by Pub. L. 113–186) requires that States and Territories submit annual aggregate data on the children and families receiving direct services under the Child Care and Development Fund. The implementing regulations for the statutorily required reporting are at 45 CFR 98.70 and 98.71. Annual aggregate reports include data elements represented in the ACF–800 reflecting the scope, type, and methods of child care delivery. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research.

Consistent with the recent reauthorization of the CCDBG statute, ACF requests extension and revision of the ACF–800 including a number of changes and clarifications to the reporting requirements and instructions. Most notably, section 658K(a)(2)(F) of the CCDBG Act now requires States to report the number of fatalities occurring among children while in the care and facility of child care providers serving CCDF children.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–800	56	1	42	2,352

Estimated Total Annual Burden Hours: 2,352.

In compliance with the requirements of Section 506(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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–10987 Filed 5–6–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0397]

Determination of Regulatory Review Period for Purposes of Patent Extension; ISTENT TRABECULAR MICRO-BYPASS STENT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for the ISTENT TRABECULAR MICRO-BYPASS STENT 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 USPTO 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 has approved for marketing the medical device ISTENT TRABECULAR MICRO-BYPASS STENT. ISTENT TRABECULAR MICRO-BYPASS STENT is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. Subsequent to this approval, the USPTO received a patent term restoration application for the ISTENT TRABECULAR MICRO-BYPASS STENT (U.S. Patent No. 6,626,858) from Glaukos Corporation, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 30, 2014, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of the ISTENT TRABECULAR MICRO-BYPASS STENT represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for the ISTENT TRABECULAR MICRO-BYPASS STENT is 2,820 days. Of this time, 1,535 days occurred during the testing phase of the regulatory review period, while 1,285 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 FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* October 7, 2004. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective October 7, 2004.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* December 19, 2008. FDA has verified the applicant's claim that the premarket approval application (PMA) for the ISTENT TRABECULAR MICRO-BYPASS STENT (PMA P080030) was initially submitted December 19, 2008.

3. *The date the application was approved:* June 25, 2012. FDA has verified the applicant's claim that PMA P080030 was approved on June 25, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.