

Leroy A. Richardson,
*Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.*

[FR Doc. 2015-10286 Filed 5-1-15; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

**Administration for Children and
 Families**

**Submission for OMB Review;
 Comment Request**

Title: Child Care Development Fund,
 CCDF; Reporting Improper Payments;
 Instructions for States.

OMB No.: 0970-0323.

Description: Section 2 of the Improper
 Payments Act of 2002 provides for
 estimates and reports of improper
 payments by Federal agencies. Subpart
 K of 45 CFR, part 98 will require States
 to prepare and submit a report of errors

occurring in the administration of CCDF
 grant funds once every three years.

The Office of Child Care (OCC) is
 completing the third 3-year cycle of case
 record reviews to meet the requirements
 for reporting under IPIA. The current
 forms and instructions expire
 September 30, 2015. OCC is submitting
 the information collection for renewal
 clearance with minor changes.
 Responders will now have additional
 guidance and clarification in the
 instructions and errors have been
 corrected. New language incorporates
 requirements from the 2014 Child Care
 and Development Fund Block Grant Act
 passed in November 2014.

Respondents: State grantees, the
 District of Columbia, and Puerto Rico

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Sampling Decisions and Fieldwork Preparation Plan	17	1	106	1,802
Record Review Worksheet	17	276	6.33	29,700.36
State Improper Authorizations for Payment Report	17	1	639	10,863
Corrective Action Plan	8	1	156	1,248

*Estimated Total Annual Burden
 Hours:* 43,613.36.

Additional Information: Copies of the
 proposed collection may be obtained 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. All requests should be
 identified by the title of the information
 collection. Email 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, Email: [OIRA_](mailto:OIRA_SUBMISSION@OMB.EOP.GOV)
SUBMISSION@OMB.EOP.GOV. Attn:
 Desk Officer for the Administration for
 Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015-10296 Filed 5-1-15; 8:45 am]

BILLING CODE 4184-01-P

**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2013-E-0785]

**Determination of Regulatory Review
 Period for Purposes of Patent
 Extension; RELAY THORACIC STENT-
 GRAFT WITH PLUS DELIVERY
 SYSTEM**

AGENCY: Food and Drug Administration,
 HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
 Administration (FDA) has determined
 the regulatory review period for the
 RELAY THORACIC STENT-GRAFT
 WITH PLUS DELIVERY 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 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://](http://www.regulations.gov)
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://](http://www.regulations.gov)
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 RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM. RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM is indicated for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy. Subsequent to this approval, the USPTO received a patent term restoration application for the RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM (U.S. Patent No. 8,062,345 B2) from Bolton Medical Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 18, 2014, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of the RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM 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 RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM is 2,852 days. Of this time, 2,529 days occurred during the testing phase of the regulatory review period, while 323 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:* December 2, 2004. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on December 3, 2004. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on December 2, 2004, which represents the IDE effective date.

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):* November 4, 2011. FDA has verified the applicant's claim that the premarket approval application (PMA) for the RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM (PMA P110038) was initially submitted November 4, 2011.

3. *The date the application was approved:* September 21, 2012. FDA has verified the applicant's claim that PMA P110038 was approved on September 21, 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 225 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**) either electronic or written comments and ask for a redetermination by July 6, 2015. 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 November 2, 2015. 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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA-2013-S-0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-10338 Filed 5-1-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2013-E-1299 and FDA-2013-E-1302]

Determination of Regulatory Review Period for Purposes of Patent Extension; CAMERON HEALTH S-ICD SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CAMERON HEALTH S-ICD SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, Rm. 3180, Silver Spring, MD 20993-0002, 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