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 Office of Scientific Integrity, Office of the
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 Prevention.*

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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](mailto:OIRA_SUBMISSION@OMB.EOP.GOV). Attn:
 Desk Officer for the Administration for
 Children and Families.

Robert Sargis,

Reports Clearance Officer.

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**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