about both risks and benefits, and no additional information) in three different promotional offers (money back guarantee and two others) in a medium prevalence medical condition (defined previously). This supplemental study will be conducted online. One type of offer examined will be money back guarantee; we will choose the other two types of promotional offers based on the results of the main study. The exact wording of the qualifying context to be examined will be determined through pretesting. This study is experimental in method: Participants will be randomly assigned to condition.

Supplementary Study Design

	Type of Offer		
Type of Context (*examples*)	Money Back Guarantee	Offer 2 To be determined	Offer 3 To be determined
Additional information about risk			
Additional information about efficacy			
Additional information about efficacy and risk			
Control: No Context			

Interviews are expected to last no more than 20 minutes. A total of 10,000 participants will be involved in the pretesting and two phases of the study. This will be a one time (rather than annual) collection of information.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretests	1,000	1	1,000	.33	330
Main study: online	3,750	1	3,750	.33	1,238
Main study: mall intercept	2,250	1	2,250	.33	743
Supplementary study	3,000	1	3,000	.33	990
Total	10,000				3,301

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–23632 Filed 9–21–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0447]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices Third-Party Review Under the Food and Drug Administration Modernization Act

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 information collection requirements for the information collection in "Medical Devices Third-Party Review under the Food and Drug Administration Modernization Act of 1997."

DATES: Submit either electronic or written comments on the collection of information by November 22, 2010.

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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

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.

Medical Devices Third-Party Review Under the Food and Drug Administration Modernization Act—Section 523 of the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0375)—Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket notifications [510(k)s]. Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) of the act (21 U.S.C. 360) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low- to moderate-risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 523 of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
Requests for Accreditation	1	1	1	24	24
510(k) reviews conducted by accredited third parties	10	26	260	40	10,400
Totals					10,424

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Section 523 of the Act	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
510(k) reviews	10	26	260	10	2,600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

I. Reporting

510(k) reviews conducted by accredited third parties

According to FDA's data in 2009, the agency has experienced that the number of 510(k)'s submitted for third-party review is approximately 260 annually, which is 26 annual reviews per each of the 10 accredited reviewers.

II. Recordkeeping

Third party reviewers are required to keep records of their review of each submission. According to FDA's in 2009, the agency anticipates approximately 260 submissions of 510(k)'s for third-party review per year.

Dated: September 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–23633 Filed 9–21–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Income Withholding for Support (IWO).

OMB No.: 0970–0154.

Description

Use of the OMB-approved Income Withholding for Support form falls under the authority of section 466 of the Act, 42 U.S.C. 666. Section 466(b)(6)(A)(ii) of the Act requires that the notice given to the employer for income withholding in IV–D cases shall be in a standard format prescribed by the Secretary, and contain only such information as may be necessary for the employer to comply with the withholding order for all IV–D cases. Section 466(a)(8)(B)(iii) of the Act requires that section 466(b)(6)(A)(ii) of the Act be applicable also to non-IV–D income withholding orders. These provisions clearly require all individuals and entities to use a form developed by the Secretary of HHS to notify employers of the income withholding order for child support in all IV–D and non-IV–D cases.

OCSE requires States' automated systems to be able to automatically generate and download data to the OMB approved income withholding form. If child support orders are established by the child support agency, necessary information is already contained within the automated system for downloading into income withholding orders. If a court or other tribunal has issued a child support order, then agency staff