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

enter the terms of the order into the automated system for use in issuing income withholding orders. Copies of the income withholding order are made for all necessary parties, and copies are transmitted to the employer/income withholder by mail or through the OCSE electronic income withholding order (e-IWO) portal.

The Income Withholding for Support form and instructions were updated for consistency and clarity in light of numerous comments suggesting changes, based on comments received during the 60-day comment period of the 1st **Federal Register** Notice publication.

Respondents: State Child Support Agencies and Tribes.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Income Withholding for Support (Form)	58	0	0	0
e-IWO Record Layouts	58	0	0	0

Estimated Total Annual Burden Hours: 0.

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. *Fax:* 202–395–6974. *Attn:* Desk Officer for the Administration for Children and Families.

Dated: September 15, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–23562 Filed 9–21–10; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0490]

Preparation for International Conference on Harmonisation Steering Committee and Expert Working Group Meetings in Fukuoka, Japan; Regional Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH Steering Committee and Expert Working Group Meetings in Fukuoka, Japan" to provide information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Fukuoka, Japan. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Fukuoka, Japan, November 6 through 11, 2010, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The public meeting will be held on October 13, 2010, from 2:30 p.m. to 4:30 p.m.

Location: The public meeting will be held at the Washington Theater at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: All participants must register with Jennifer Haggerty, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, email: *jennifer.haggerty@fda.hhs.gov*, or FAX: 301–595–7937.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations to Jennifer Haggerty (see *Contact Person*) by 5 p.m. e.s.t. on October 11, 2010.

If you need special accommodations due to a disability, please contact Jennifer Haggerty (see *Contact Person*) at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with