ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
On-line Survey of SCF Grantees	84	1	0.25	21
Telephone Interview of SCF Grantees	84	1	1.5	126
On-line Survey of Faith-based and Community Organizations (FBCOs)	1,000	1	0.5	500

Estimated Total Annual Burden Hours: 647.

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:* 202–395–7285, *E-mail: OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–3745 Filed 2–17–11; 8:45 am]

BILLING CODE 4184–01–P

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: Non-IV–D Custodial Parties and Employers.

Previous iterations of the IWO omitted employers and non-IV–D CPs or their representatives, including attorneys or other entities issuing IWOs on behalf of CPs, as respondents; however, upon further review it has been determined that the impact on employers and non-IV–D CPs should be included in this information collection. This is based on the requirement that employers complete the "Notification of Termination/Income Status" section of the IWO and that non-IV–D CPs or their representative issuing IWOs do not have the information required to complete the IWO contained in an automated system and therefore are required to manually issue IWOs to employers/income withholders. The annual burden estimates for employers and CPs is captured in number 12.

ANNUAL BURDEN ESTIMATES

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response (min)	Total burden hours
Employers	1,232,622	8	2	312,264
Non-IV–D CPs	1,969,044	1	5	164,087

Estimated Total Annual Burden Hours: 476,351.

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: 202–395–7285, E-mail: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0082]

Draft Guidance for Industry on Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies." The draft guidance is intended to assist the pharmaceutical industry and other investigators engaged in new drug development in evaluating how variations in the human genome could affect the clinical pharmacology properties and clinical responses of drugs.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 19, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Lawrence J. Lesko, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3178, Silver Spring, MD 20993–0002, 301–796–1565; or

Shiew-Mei Huang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3188, Silver Spring, MD 20993–0002, 301–796–1541; or

Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM–17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies." Pharmacogenomics (PGx) broadly refers to the study of variations of DNA and RNA characteristics and their relation to drug exposure and/or response. Drug exposure refers to either the administered dose or levels in a body tissue or fluid (*e.g.,* blood, plasma, cerebrospinal fluid). Drug response results from the interplay of pharmacokinetics (*e.g.,* drug absorption, metabolism, and excretion), and pharmacodynamics (*i.e.,* all of the effects of the drug on various physiologic and pathologic processes, including effectiveness and adverse effects). Genetic variations can also influence the exposure-response (E/R) relationship of drugs. PGx studies can enhance the understanding of interindividual differences in the efficacy and safety of investigational drugs.

Drug development is commonly described as going through "phases" (21 CFR 312.21). The first two phases collect information about safety and dosing, so that the larger, later (phase 3) studies (the adequate and well-controlled studies needed to support marketing approval) can gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Much of the genomic information collected and assessed during the early phases is often described as "exploratory." Phase 2 studies that suggest genomic influences can lead to phase 3 trials that incorporate findings into prespecified hypotheses, such as enriching the study with genomically defined individuals, determining dose based on demonstrated variability in earlier studies, and defining a priori hypothesis testing of a primary endpoint in a genomic subset.

PGx information obtained from genomic investigations during the course of drug development (and from postmarketing studies) can improve the effectiveness and safety of drugs by identifying patients at high risk for a serious adverse event or absence of benefit; improving the benefit/risk relationship of drugs by using genomic tests to identify patients most likely to respond, or unable to respond to a drug; and by helping to select optimal doses based on genotype-driven differences in PK (pharmacodynamics) and/or PD (pharmacodynamics) of a drug. An important prerequisite to successful use of genetic information in drug development is appropriate collection and storage of DNA samples from all clinical trials, both exploratory and the adequate and well-controlled studies intended to support effectiveness and safety.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on conducting pharmacogenomic studies in