Report	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
BHPr Performance Report	1,000	1	1,000	24	24,000
Total	1,000		1,000		24,000

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: June 24, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–15830 Filed 6–29–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Order/Notice to Withold Income for Child Support.

OMB No.: 0970–0154.

Description: The Social Security Act requires that child support agencies, courts, tribes, private attorneys and all other entities use the OMB approved federal Income Withholding for Support when ordering or sending notice to employers/income withholders of the requirement to withhold income for child support. 42 U.S.C. 666(b)(6)(i) and (ii) requires the use of the Income Withholding for Support form in all cases enforced by child support agencies where payment is made by income withholding, whether the case is processed administratively or through the court. 42 U.S.C. 666(a)(8)(B)(iii) provides that the requirements of section 666(b)(6) are applicable to cases not being enforced by the state child support agency or private cases with initial orders issued on or after January 1, 1994. The form promotes standardization and is used for title IV–D and non-IV–D cases that require income withholding.

The Income Withholding for Support has been modified to address items identified by states and employers/income withholders. The shading on the form was removed because it obscures information when the form is faxed or scanned to an employer/income withholder. Also, a check box has been added to allow employers/income withholders to return the Income Withholding for Support form if payments are not directed through the State Disbursement Unit (SDU) as required by federal and state laws. With the addition of a mechanism to return Income Withholding for Support forms, payment instructions that conflict with federal and state laws will be addressed.

Respondents: Not applicable.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours

Estimated Total Annual Burden Hours: 0.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. *E-mail address: infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 24, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–15798 Filed 6–29–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0117]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry Entitled Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under

the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by July 30, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-new and title Guidance for Industry entitled "Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry entitled "Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims"—21 CFR 201.56 and 201.57 (OMB Control Number 0910–New)

This guidance is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension. With few exceptions, current labeling for antihypertensive drugs includes only the information that these drugs are indicated to reduce blood pressure; the labeling does not include information on the clinical benefits related to cardiovascular outcomes expected from such blood pressure reduction. However, blood pressure control is well established as beneficial in preventing serious cardiovascular events, and inadequate treatment of hypertension is acknowledged as a significant public health problem. FDA believes that the appropriate use of these drugs can be encouraged by making the connection between lower blood pressure and improved cardiovascular outcomes more explicit in labeling. The intent of the guidance is to provide common labeling for antihypertensive drugs except where differences are clearly supported by clinical data. The guidance encourages applicants to submit labeling supplements containing the new language.

In the **Federal Register** of March 13, 2008 (73 FR 13546), FDA published the draft guidance entitled "Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims." The draft guidance contained no information collection subject to OMB review under the PRA. The final guidance, however, contains two new provisions that are subject to OMB review and approval under the PRA, and one new provision that would be exempt from OMB review. Under the PRA, FDA must first obtain OMB approval for this information collection before we may issue the final guidance.

(1) Section IV.C of the guidance requests that the CLINICAL STUDIES section of the Full Prescribing Information of the labeling should include a summary of placebo- or active-controlled trials showing evidence of the specific drug's effectiveness in lowering blood pressure. If trials demonstrating cardiovascular outcome benefits exist, those trials also should be summarized in this section. Table 1 in section V of the guidance contains the specific drugs for which FDA has concluded that such trials exist. If there are no cardiovascular outcome data to cite, one of the following two paragraphs should appear:

"There are no trials of [DRUGNAME] or members of the [name of pharmacologic class] pharmacologic class demonstrating reductions in cardiovascular risk in patients with hypertension," or "There are no trials of [DRUGNAME] demonstrating reductions in cardiovascular risk in patients with hypertension, but at least one pharmacologically similar drug has demonstrated such benefits."

In the latter case, the applicant's submission generally should refer to table 1 in section V of the guidance. If the applicant believes that table 1 is incomplete, it should submit the clinical evidence for the additional information to Docket No. FDA–2008–D–0150. The labeling submission should reference the submission to the docket. FDA estimates that no more than one submission to the docket will be made annually from one company, and that each submission will take approximately 10 hours to prepare and submit. Concerning the recommendations for the CLINICAL STUDIES section of the Full Prescribing Information of the labeling, FDA regulations at §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) require such labeling, and the information collection associated with these regulations is approved by OMB under OMB Control Number 0910–0572.

(2) Section VI.B of the guidance requests that the format of cardiovascular outcome claim prior approval supplements submitted to FDA under the guidance should include the following information:

1. A statement that the submission is a cardiovascular outcome claim supplement, with reference to the guidance and related Docket No. FDA–2008–D–0150
2. Applicable FDA forms (e.g., 356h, 3397)
3. Detailed Table of Contents
4. Revised labeling:

a. Include draft revised labeling conforming to the requirements in §§ 201.56 and 201.57

b. Include marked-up copy of the latest approved labeling, showing all additions and deletions, with annotations of where supporting data (if applicable) are located in the submission

FDA estimates that approximately 70 cardiovascular outcome claim supplements will be submitted annually from approximately 30 different companies, and that each supplement will take approximately 4 hours to prepare and submit. The guidance also recommends that other labeling changes (e.g., the addition of adverse event data) should be minimized and provided in separate supplements, and that the revision of labeling to conform to §§ 201.56 and 201.57 may require substantial revision to the ADVERSE REACTIONS or other labeling sections.

(3) Section VI.C of the guidance states that applicants are encouraged to include the following statement in promotional materials for the drug.

"[DRUGNAME] reduces blood pressure, which reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals."

The inclusion of this statement in the promotional materials for the drug would be exempt from OMB review based on 5 CFR 1320.3(c)(2), which states that "The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included * * *" within the definition of "collection of information."

In the **Federal Register** of March 22, 2010, (75 FR 13547), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Submission to Docket No. FDA–2008–D–0150	1	1	1	10	10
Cardiovascular Outcome Claim Supplement Submission	30	2.33	70	4	280
Total					290

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

Dated: June 24, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15859 Filed 6–29–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel NIAAA Fellowship & Training Member Conflict Applications.

Date: July 8, 2010.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, PhD, Chief, Extramural Project Review Branch, EPRB, NIAAA, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS).

Dated: June 17 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–15610 Filed 6–29–10; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; SHINE.

Date: July 15, 2010.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Richard D. Crosland, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/ Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–594–0635, *Rc218u@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: June 24, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–15899 Filed 6–29–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Issues in the Design and Conduct of Clinical Trials for Antibacterial Drug Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding scientific issues in the design and conduct of clinical trials for antibacterial drug development. The public workshop is intended to provide information for and gain perspectives from health care providers, researchers, academia, industry, and regulators on various aspects of design and conduct of clinical trials for antibacterial drugs. The workshop will focus on the design and conduct of non-inferiority (NI) clinical