Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

[FR Doc. 2010–26955 Filed 10–25–10; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

Name of Committee: HIT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the HIT Policy Committee.

Date and Time: The meeting will be held on November 30, 2010, from 9 a.m. to 3 p.m./Eastern Time.

Location: The meeting will be conducted virtually only. Dial into the meeting: 1–877–705–6006; webcast: *http://altarum.adobeconnect.com/HITstandards.*

Contact Person: Judy Sparrow, Office of the National Coordinator, HHS, 330 C Street, SW., Washington, DC 20201, 202–205–4528, Fax: 202–690–6079, e-mail: *judy.sparrow@hhs.gov.* Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will hear reports from its workgroups, including the Clinical Operations, Vocabulary Task Force, Implementation, and Enrollment Workgroups. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at *http://healthit.hhs.gov.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 24, 2010. Oral comments from the public will be scheduled between approximately 2 and 3 p.m./Eastern Time. Time allotted for each presentation will be limited to three minutes each. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public hearing session, ONC will take written comments after the meeting until close of business.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Judy Sparrow at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://healthit.hhs.gov* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: October 18, 2010.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2010–26918 Filed 10–25–10; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0541]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Special Protocol Assessment

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.

DATES: Fax written comments on the collection of information by November 26, 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 0910–0470. 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 on Special Protocol Assessment—OMB Control Number 0910–0470—Extension

The "Guidance for Industry on Special Protocol Assessment" describes Agency procedures to evaluate issues related to the adequacy (*e.g.,* design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the Agency to act on such requests. The guidance provides information on how the Agency interprets and applies provisions of the Food and Drug Administration

Modernization Act of 1997 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products. The guidance describes the following two collections of information: (1) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol and (2) the submission of a request for special protocol assessment.

Notification for a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in Agency assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days prior to submitting the request. With such notification, the sponsor should submit relevant background information so that the Agency may review reference material related to carcinogenicity protocol design prior to receiving the carcinogenicity protocol.

Request for Special Protocol Assessment

The guidance asks that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to the Agency in triplicate with Form FDA 1571 attached. The guidance also suggests that the sponsor submit the cover letter to a request for special protocol assessment via facsimile to the appropriate division in CDER or CBER. Agency regulations (21 CFR 312.23(d)) state that information provided to the Agency as part of an IND is to be submitted in triplicate and with the appropriate cover form, Form FDA 1571. An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting from the preparation and submission of an IND under part 312 have been estimated by FDA and the reporting and recordkeeping burden has been approved by OMB under OMB control number 0910–0014.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via facsimile to the appropriate division in CDER or CBER to enable Agency staff to prepare for the arrival of the protocol for assessment. The Agency recommends that a request for special protocol assessment be submitted as an amendment to an IND for two reasons: (1)To ensure that each request is kept in the administrative file with the entire IND and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the Agency's tracking databases enables the appropriate Agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.

The guidance recommends that the following information should be submitted to the appropriate Center with each request for special protocol assessment so that the Center may quickly and efficiently respond to the request:

- Questions to the Agency concerning specific issues regarding the protocol; and
- All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization and relevant manufacturing data.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the Agency under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act (42 U.S.C. 262) who requests special protocol assessment.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for requests for special protocol assessment.

Notification for a Carcinogenicity Protocol. Based on data collected within CDER and CBER, including the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols submitted in fiscal years (FY) 2007, 2008, and 2009, CDER estimates that it will receive approximately 60 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 28 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

Requests for Special Protocol Assessment. Based on data collected within CDER and CBER, including the number of requests for special protocol assessment submitted in FY 2007, 2008, and 2009, CDER estimates that it will receive approximately 372 requests for special protocol assessment per year from approximately 216 sponsors. CBER estimates that it will receive approximately 10 requests from approximately 10 sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the Agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on the Agency's experience with these submissions, FDA estimates approximately 15 hours on average would be needed per response.

In the **Federal Register** of July 13, 2010 (75 FR 39949), 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 as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Notification for Carcinogenicity Protocols	29	2.10	61	8	488

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Requests for Special Protocol Assessment	226	1.69	382	15	5,730
Total					6,218

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

Dated: October 20, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–26985 Filed 10–25–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Award of a Single-source Program Expansion Supplement Grant to the Research Foundation of the State University of New York (SUNY) at Albany, NY, for the National Child Welfare Workforce Institute (NCWWI)

AGENCY: Children's Bureau, ACYF, ACF, HHS.

ACTION: Notice.

CFDA Number: 93.648.

Legislative Authority: Section 426(a)(1)(C) of the Social Security Act, as amended [42 U.S.C. 626(a)(1)(C)].

Amount of Award: $480,000.

Project Period: September 30, 2010 through September 29, 2011.

Summary: The Administration for Children and Families (ACF), Children's Bureau (CB) announces the award of a single-source program expansion supplement grant to the Research Foundation at the State University of New York (SUNY) at Albany, National Child Welfare Workforce Institute (NCWWI), Albany, NY, to support additional Bachelor's of Social Work (BSW) and Master's of Social Work (MSW) traineeship programs at three universities.

The NCWWI was awarded a cooperative agreement in FY 2008 as the result of a competition. Under the cooperative agreement, NCWWI identifies promising practices in child welfare workforce development, identifies and facilitates leadership training for middle managers and child welfare supervisors, administers BSW and MSW traineeships at multiple universities, engages national peer networks, supports strategic dissemination of effective and promising workforce practices, and advances knowledge through collaboration and evaluation.

As part of the program, NCWWI provides stipend to public and/or non-profit institutions of higher education with accredited social work education programs for traineeships for professional education for current or prospective child welfare practitioners enrolled in BSW or MSW social work programs. During the course of traineeship and after obtaining the degree for which the stipend was awarded, stipend recipients must participate in regular training at a child welfare agency and work for a child welfare agency for a period that is equivalent to the period of the supported traineeship.

The three programs to be awarded traineeships with the expansion supplement award are:

Northeastern State University, Tahlequah, OK. This program provides for a child welfare specialization at the BSW level. Students are recruited from American Indian Tribes for work in Tribal child welfare agencies.

University of South Dakota, Vermillion, SD. The BSW program includes a special emphasis on serving rural and Native American populations. Distance education is being used to reach remote geographic areas.

New Mexico State University, Las Cruces, NM. This combined BSW and MSW program is selecting trainees that are sensitive to Hispanic/Chicano heritage and are Spanish speaking. With special field instructors who can address child welfare skills, Hispanic culture, and the Spanish language, this project is serving an overrepresented population in the child welfare system.

Contact for Further Information: Jane Morgan, Children's Bureau, 1250 Maryland Avenue, SW., Washington, DC 20024. Telephone: 202–205–8807. E-mail: *jane.morgan@acf.hhs.gov.*

Dated: October 14, 2010.

Bryan Samuels,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 2010–26936 Filed 10–25–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel, Member Conflict: Auditory Neuroscience.

Date: October 27, 2010.

Time: 2:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: John Bishop, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 20, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–27040 Filed 10–25–10; 8:45 am]

BILLING CODE 4140–01–P