ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Interview Protocol	Faculty	100	1	2	200
Interview Protocol	Doctoral Student Graduates	100	1	2	200
Total					400

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E9–25028 Filed 10–16–09; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT Standards Committee's Implementation Workgroup 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 subcommittee 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's Implementation Workgroup.

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. The Implementation Workgroup is charged with benchmarking adoption rates for proposed standards across diverse settings; soliciting public input on what stakeholders need to lower the barriers to standards adoption; evaluating the degree to which proposed standards achieve policy objectives; and establishing an ongoing process to gather public input to inform future standards development, revisions to existing standards, or guidance on tools to minimize the cost of adoption.

Date and Time: The meeting will be held on October 29, 2009, from 9 a.m. to 3 p.m./Eastern Time.

Location: The Omni Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC. The hotel telephone number is 202–234–0700.

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 Implementation Workgroup will be hearing testimony from stakeholder groups, such as purchasers, vendors, and users, on health information technology adoption experiences with the proposed standards. The Workgroup intends to monitor the adoption rate of proposed standards, identify opportunities to accelerate implementation, and establish a continuous feedback loop on the development of new or revised standards.

In addition to soliciting verbal and formal written comments at the hearing, the Workgroup will use a Web-based tool to engage the public. The ONC is setting up a Web-based tool to engage the public in the topic; please visit the ONC Web site closer to the meeting date for additional information.

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 subcommittee meeting, and the background material will be posted on ONC's Web site after the meeting, at *http://healthit.hhs.gov*. The meeting will be available via Webcast; visit *http://healthit.hhs.gov* for instructions on how to listen via telephone or Web.

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 from October 29th until November 12, 2009. Oral comments from the pubic will be scheduled at the close of the meeting on October 29, 2009. Time allotted for each presentation may be limited. 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 on that day.

Persons attending 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 13, 2009.

Judith Sparrow,

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

[FR Doc. E9–25051 Filed 10–14–09; 4:15 pm]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation for Members of the National Vaccine Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

Authority: 42 U.S.C. 300aa–5, Section 2105 of the Public Health Service (PHS)

Act, as amended. The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The National Vaccine Program Office (NVPO), a program office within the Office of Public Health and Science, DHHS, is soliciting nominations of qualified candidates to be considered for appointment as public members to the National Vaccine Advisory Committee (NVAC). The activities of this Committee are governed by the Federal Advisory Committee Act (FACA). Management support for the activities of this Committee is the responsibility of the NVPO.

Consistent with the National Vaccine Plan, the Committee advises and makes recommendations to the Assistant Secretary for Health in his capacity as the Director of the National Vaccine Program, on matters related to the Program's responsibilities. Specifically, the Committee studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States; recommends research priorities and other measures to enhance the safety and efficacy of vaccines. The Committee also advises the Assistant Secretary for Health in the implementation of Sections 2102 and 2103 of the PHS Act; and identifies annually the most important areas of government and non-government cooperation that should be considered in implementing Sections 2102 and 2103 of the PHS Act.

DATES: Nominations for membership on the Committee must be received no later than 5 p.m. EDT on November 16, 2009, at the address below.

ADDRESSES: *All nominations should be mailed or delivered to:* Bruce G. Gellin, M.D., M.P.H., Executive Secretary, NVAC, Office of Public Health and Science, Department of Health and Human Services, 200 Independence Avenue, SW., Room 715–H, Hubert H. Humphrey Building, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Krull, Public Health Advisor, National Vaccine Program Office, Department of Health and Human Services, 200 Independence Avenue, SW., Room 715–H, Hubert H. Humphrey Building, Washington, DC 20201; (202) 690–5566; *nvpo@hhs.gov.*

A copy of the Committee charter which includes the Committee's structure and functions as well as a list of the current membership can be obtained by contacting Ms. Krull or by accessing the NVAC Web site at: *www.hhs.gov/nvpo/nvac.*

SUPPLEMENTARY INFORMATION:

Committee Function, Qualifications, and Information Required: As part of an ongoing effort to enhance deliberations and discussions with the public on vaccine and immunization policy, nominations are being sought for interested individuals to serve on the Committee as public members. Individuals selected for appointment to the Committee will serve as voting members. The Committee is composed of 15 public members, including the Chair, and two representative members. In accordance with the Committee charter, public members shall be selected from individuals who are engaged in vaccine research or the manufacture of vaccines, or who are physicians, members of parent organizations concerned with immunizations, representatives of state or local health agencies or public health organizations. Representative members shall be selected from the vaccine manufacturing industry who are engaged in vaccine research or the manufacture of vaccines. Individuals selected for appointment to the Committee can be invited to serve terms of up to four years.

All NVAC members are authorized to receive the prescribed per diem allowance and reimbursement for travel expenses that are incurred to attend meetings and conduct authorized Committee-related business, in accordance with Standard Government Travel Regulations. Individuals who are appointed to serve as public members are authorized also to receive honorarium for attending Committee meetings and to carry out other authorized Committee-related business. Individuals who are appointed to serve as representative members for a particular interest group or industry are not authorized to receive honorarium for the performance of these duties.

This announcement is to solicit nominations of qualified candidates to fill positions on the NVAC that are scheduled to be vacated in the public member category. The positions are scheduled to be vacated on March 31, 2010.

Nominations

In accordance with the charter, persons nominated for appointment as members of the NVAC should be among authorities knowledgeable in areas related to vaccine safety, vaccine effectiveness, and vaccine supply. Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address and daytime telephone number, and the home and/or work address, telephone number, and e-mail address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae.

Individuals can nominate themselves for consideration of appointment to the Committee. All nominations must include the required information. Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable. Applications cannot be submitted by facsimile. The names of Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made that a broad representation of geographic areas, gender, ethnic and minority groups, and the disabled are given consideration for membership on HHS Federal advisory committees. Appointment to this committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as public members of Federal advisory committees. Individuals appointed to serve as public members of Federal advisory committees are classified as special Government employees (SGEs). SGEs are Government employees for purposes of the conflict of interest laws. Therefore, individuals appointed to serve as public members of NVAC are subject to an ethics review. The ethics review is conducted to determine if the individual has any interests and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee. Individuals appointed to serve as public members of the

Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: October 6, 2009.

Bruce Gellin,

Director, National Vaccine Program Office, Executive Secretary, National Vaccine Advisory Committee.

[FR Doc. E9–25079 Filed 10–16–09; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0302] (formerly Docket No. 2007D–0185)

Guidance for Industry and Review Staff on Labeling for Human Prescription Drug and Biological Products—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and review staff entitled ''Labeling for Human Prescription Drug and Biological Products—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information.'' This guidance is intended to provide applicants and review staff with a definition of established pharmacologic class and to help them identify the most appropriate word (term) or phrase that describes the established pharmacologic class for a drug or biological product for inclusion in the *Indications and Usage* section of Highlights of Prescribing Information (*Highlights*) of approved labeling. This guidance finalizes the draft guidance published in the **Federal Register** on May 16, 2007.

DATES: Submit electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Laurie B. Burke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6462, Silver Spring, MD 20993–0002, 301–796–0136; or

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and review staff entitled ''Labeling for Human Prescription Drug and Biological Products—determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information.'' This guidance is intended to provide applicants and review staff with a definition of established pharmacologic class and to help them identify the most appropriate word (term) or phrase that describes the established pharmacologic class for a drug or biological product for inclusion in the *Indications and Usage* section of *Highlights* of approved labeling, as required under 21 CFR 201.57(a)(6).

In January 2006, FDA published a final rule that amended the requirements for the content and format of labeling for human prescription drug and biological products.[1]

The new labeling format is intended to make it easier for health care professionals to access, read, and use the information in prescription drug labeling, thereby facilitating professionals' use of labeling to make prescribing decisions.

The rule requires that the following statement appear under the *Indications and Usage* section of *Highlights* if a drug is a member of an established pharmacologic class:[2]

''(Drug) is a (name of class) indicated for (indication(s)).''

If the drug is not a member of an established pharmacologic class, the name of class component of this statement should be omitted.

Knowing the established pharmacologic class can provide health care professionals with important information about what to expect from a drug and how it relates to other therapeutic options. Such information can also help reduce the risk of duplicative therapy and drug interactions. This guidance provides recommendations for identifying the established pharmacologic class and its appropriate term for inclusion in the *Indications and Usage* section of *Highlights*.

A draft version of this guidance was made available for public comment in 2007 (72 FR 27576, May 16, 2007). All of the public comments we received have been considered and the guidance has been revised as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information collection associated with the final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'' is approved by OMB under Control Number 0910–0572. The submission of prior-approval labeling supplements, as described in section VI of the guidance, is approved by OMB under Control Numbers 0910–0001 and 0910–0338.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic

[1] See ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'' (71 FR 3922, January 24, 2006; 21 CFR parts 201, 314, 601).

[2] See § 201.57(a)(6).