

Web site for the FACA database is <http://fido.gov/facadatabase/>.

Dated: June 10, 2010.

**Donald B. Moulds,**

*Acting Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2010-14447 Filed 6-15-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the National Coordinator for Health Information Technology; HIT Policy Committee's Workgroup Meetings; Notice of Meetings

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

**ACTION:** Notice of meetings.

This notice announces forthcoming subcommittee meetings of a Federal advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meetings will be open to the public via dial-in access only.

*Name of Committees:* HIT Policy Committee's Workgroups: Meaningful Use, Privacy & Security Policy, Adoption/Certification, Enrollment, Privacy & Security Tiger Team, and Nationwide Health Information Infrastructure (NHIN) workgroups.

*General Function of the Committee:* to provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.

*Date and Time:* The HIT Policy Committee Workgroups will hold the following additional public meetings during June 2010: June 22nd Privacy & Security Tiger Team, 10 a.m. to 1 p.m./ET; June 25th Enrollment Workgroup, 9 a.m. to 10 a.m./ET; June 28th Enrollment Workgroup, 10 a.m. to 1 p.m./ET and Privacy & Security Tiger Team, 2 p.m. to 4 p.m./ET. In addition, the June 28th Privacy & Security Policy Workgroup, 2 p.m. to 4 p.m./ET, has been cancelled.

*Location:* All workgroup meetings will be available via webcast; for instructions on how to listen via telephone or Web visit <http://healthit.hhs.gov>. Please check the ONC

Web site for additional information as it becomes available.

*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](mailto:judy.sparrow@hhs.gov) Please call the contact person for up-to-date information on these meetings. A notice in the **Federal Register** about last minute modifications that affect a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

*Agenda:* The workgroups will be discussing issues related to their specific subject matter, e.g., meaningful use, the NHIN, privacy and security, or enrollment. If background materials are associated with the workgroup meetings, they will be posted on ONC's Web site prior to 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 workgroups. Written submissions may be made to the contact person on or before two days prior to the workgroups' meeting date. Oral comments from the public will be scheduled at the conclusion of each workgroup meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public session, ONC will take written comments after the meeting until close of business on that day.

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. No. 92-463, 5 U.S.C., App. 2).

Dated: June 8, 2010.

**Judith Sparrow,**

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

[FR Doc. 2010-14397 Filed 6-15-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Vaccine Advisory Committee Meetings

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

**ACTION:** Notice of meetings.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold two teleconference meetings. The meetings are open to the public. Pre-registration is not required, however, individuals who wish to participate in the public comment sessions should either e-mail [nvpo@hhs.gov](mailto:nvpo@hhs.gov) or call 202-690-5566 to register.

**DATES:** The meeting dates are:

1. July 27, 2010, 1 p.m.–2 p.m. EDT.
2. August 25, 2010, 1 p.m.–2 p.m. EDT.

**ADDRESSES:** The meetings will occur by teleconference. To attend, please call 1-888-677-1385, passcode "NVAC."

**FOR FURTHER INFORMATION CONTACT:**

Daniel Salmon, National Vaccine Program Office, Department of Health and Human Services, Room 715-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Phone: (202) 690-5566; Fax: (202) 260-1165; e-mail: [nvpo@hhs.gov](mailto:nvpo@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. Section 300aa-1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The National Vaccine Advisory Committee was established to provide advice and make recommendations to the Director of the National Vaccine Program, on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

These are special meetings of the NVAC. Discussions will focus on the work of the Vaccine Safety Risk Assessment Working Group (VSRAWG) and the reports that it generates. The reports will summarize the work to-date of the H1N1 VSRAWG reviewing H1N1 safety monitoring data. These NVAC meetings may also include topics beyond the VSRAWG such as the

National Vaccine Plan and updates from other Working Groups. If there is a change in meeting dates this information will be posted on the NVAC Web site (<http://www.hhs.gov/nvpo/nvac/>) as soon as the pertinent information becomes available.

For these special meetings, members of the public are invited to attend by teleconference via a toll-free call-in phone number. The call-in number will be operator assisted to provide members of the public the opportunity to provide comments to the Committee. Public participation and ability to comment will be limited to space and time available. Public comment will be limited to no more than three minutes per speaker. Pre-registration is required for public comment only. Individuals who plan to attend and need special assistance, such as accommodation for hearing impairment or other reasonable accommodations, should notify the designated contact person at least one week prior to the meeting.

Any members of the public who wish to have printed material distributed to NVAC should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business one week before each meeting (conference call). A draft agenda and any additional materials will be posted on the NVAC Web site (<http://www.hhs.gov/nvpo/nvac/>) prior to the meeting.

Dated: June 1, 2010.

**Bruce Gellin,**

*Deputy Assistant Secretary for Health, Director, National Vaccine Program Office, Executive Secretary, NVAC.*

[FR Doc. 2010-14472 Filed 6-15-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0266]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer Print Advertisements for Prescription Drugs**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the

PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs. This study is designed to investigate efficacy and effectiveness information of prescription drugs as conveyed to healthcare providers through approved labeling and to consumers through print advertisements.

**DATES:** Submit either electronic or written comments on the collection of information by August 16, 2010.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed 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.

#### **Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs—New**

FDA regulations require that an advertisement that makes claims about a prescription drug include a "fair balance" of information about the benefits and risks of the advertised product, in terms of both content and presentation (§ 202.1(e)(5)(ii) (21 CFR 202.1(e)(5)(ii)). In past research, FDA has focused primarily on the risk component of the risk-benefit ratio. In the interest of thoroughly exploring the issue of fair balance, however, the presentation of effectiveness, or benefit, information is equally important.

The act requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks.<sup>1</sup> By its nature, the presentation of this risk information is likely to evoke active tradeoffs by consumers, i.e., comparisons with the perceived risks of not taking treatment, and comparisons with the perceived benefits of taking a treatment.<sup>2</sup> Because FDA has an interest in fostering safe and proper use of prescription drugs, an activity that engages both risks and benefits, an in-depth understanding of consumers' processing of this information is central to this regulatory task.

Research and guidance to sponsors on how to present benefit and efficacy information in prescription drug advertisements is limited. For example, "benefit claims," broadly defined, appearing in advertisements are often presented in general language that does not inform patients of the likelihood of efficacy and are often simply variants of

<sup>1</sup> For prescription drugs and biologics, the act requires advertisements to contain "information in brief summary relating to side effects, contraindications, and effectiveness" (21 CFR 202.1(e)(1)).

<sup>2</sup> See Schwartz, L., S. Woloshin, W. Black, et al., "The Role of Numeracy in Understanding the Benefit of Screening Mammography," *Annals of Internal Medicine*, 127(11), 966-72, 1997.