

but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;

(2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of his research contribution. A copy of the supervisory plan also must be submitted to ORI by the institution. Respondent agreed that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Standards Subcommittee.

Time and Date: July 19, 2010 9 a.m.-5 p.m. July 20, 2010 8:30 a.m.-5 p.m. July 21, 2010 9 a.m.-5 p.m. (committee discussion)

Place: Hamilton Crowne Plaza Hotel, 1001 14th Street, NW., Washington, DC 20005, (202) 682-0111.

Status: Open.

Purpose: The purpose of this upcoming meeting of the Subcommittee on Standards is to receive industry input on a unique health plan identifier to be used in HIPAA standard transactions, and on new operating rules for standards, and their authoring organizations. The Subcommittee will hear testimony from individuals, organizations and associations on these matters. The subcommittee will meet for three consecutive days for which a variety of panels are scheduled; day one will focus on the unique health plan identifier, day two will concentrate on authoring organizations and operating rules for eligibility and health claim status, and day

three of the meeting will be reserved for Subcommittee discussion and deliberation.

The NCVHS has been named in the Patient Protection and Affordable Care Act (ACA) of 2010 to review and make recommendations on several HIPAA standards and electronic transactions. This meeting will support these activities in the development of a set of recommendations for the Secretary, as required by section 1104 of the ACA. Text of the ACA can be found at http://dpc.senate.gov/dpcdoc-sen_health_care_bill.cfm.

Contact Person For More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Lorraine Doo, lead staff for the Standards Subcommittee, NCVHS, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Baltimore, Maryland, 21244, telephone (410) 786-6597 or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: June 29, 2010.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0174]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug; Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed

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 August 9, 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 0910-0513. 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.

Applications for FDA Approval to Market a New Drug; Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed—OMB Control Number 0910-0513—Extension

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(1)) requires all new drug application (NDA) applicants to file, as part of the NDA, "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture[,] use, or sale of the drug." Section 505(c)(2) of the act imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. Under section 505(b)(1) of the act, we publish patent information after approval of an NDA in the list entitled "Approved Drug Products With Therapeutic Equivalence Evaluations"