

Dated: August 8, 2011.

**Judith Sparrow,**

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

[FR Doc. 2011-20811 Filed 8-15-11; 8:45 am]

**BILLING CODE 4150-45-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **HIT Standards 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 Standards Committee's Workgroups: Clinical Operations, Vocabulary Task Force, Clinical Quality, Implementation, and Privacy & Security Standards workgroups.

*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 HIT Standards Committee Workgroups will hold the following public meetings during September 2011: September 22nd Implementation Workgroup, 3 to 5 p.m./ET; TBD other Workgroups' calls.

*Location:* All workgroup meetings will be available via Webcast; visit <http://healthit.hhs.gov> for instructions on how to listen via telephone or Web. Please check the ONC Web site for additional information and schedules 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., clinical operations, vocabulary standards, clinical quality, implementation opportunities and challenges, and privacy and security standards activities. 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 dates. 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. 92-463, 5 U.S.C., App. 2).

Dated: August 8, 2011.

**Judith Sparrow,**

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

[FR Doc. 2011-20815 Filed 8-15-11; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2011-N-0555]**

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Extra Label Drug Use in Animals**

**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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements associated with extra label drug use in animals.

**DATES:** Submit either electronic or written comments on the collection of information by October 17, 2011.

**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:**

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, [Juanmanuel.vilela@fda.hhs.gov](mailto:Juanmanuel.vilela@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, including each proposed extension of an existing 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.

**Extra Label Drug Use in Animals—21 CFR Part 530 (OMB Control Number 0910-0325—Extension)**

The Animal Medicinal Drug Use Clarification Act of 1994 allows a

veterinarian to prescribe the extra-label use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extra-label use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extra-label use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level. Although to date, we have not established a safe level for a residue from the extra-label use of any new animal drug, and therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are

therefore estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal and/or State Agencies, academia, or individuals.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
530.22(b) .....	2	1	2	4,160	8,320

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 10, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-20813 Filed 8-15-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0568]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study: Disease Information in Branded Promotional Material**

**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 research entitled "Experimental Study: Disease Information in Branded Promotional Material." The proposed research will explore the nature of

including information about a disease and promotional information about a specific drug treatment in the same advertising piece.

**DATES:** Submit either electronic or written comments on the collection of information by October 17, 2011.

**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., P150-400B, Rockville, MD 20850, 301-796-3972, [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.

**Experimental Study: Disease Information in Branded Promotional Material—(OMB Control Number 0910-New)**

*Regulatory Background:* Section 1701(a)(4) of the Public Health Service