the draft guidance. We estimate that the submission of each summary level clinical site dataset will take approximately 26 hours to prepare.

Initial preparation of the summary level clinical site dataset would involve the development of new SOPs for the preparation of the summary level clinical site dataset. We estimate that 75 applicants would take approximately 12 hours to develop and subsequently 1 hour annually to maintain and update the SOP(s). The summary level clinical site dataset submitted with each application would likely involve additional quality assurance procedures, which would add approximately 1 hour for each submission.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 312 have been approved under OMB control number 0910–0014; the collections of information in part 314 have been approved under OMB control number 0910–0001.

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

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Activity	Number of respondents (i.e. applicants)	Number of responses per respondent (i.e., applications)	Total responses	Hours per response	Total hours
Summary Level Clinical Site Dataset Submissions	75	1.3	96	26	2,496
Dataset Quality Assurance	75	1.3	96	1	96
Total					2,592

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total records	Hours per recordkeeper	Total hours
Develop Initial SOP(s)	75	1	75	12	900
Maintain and Update SOP(s)	75	1	75	1	75
Total					975

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

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: December 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30510 Filed 12–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0548]

Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public. This meeting is being rescheduled due to the postponement of the October 29–30, 2012, Drug Safety and Risk Management Advisory Committee meeting due to unanticipated weather conditions caused by Hurricane Sandy.

Name of Committee: Drug Safety and Risk Management Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 24, 2013, from 8 a.m. to 6 p.m., and January 25, 2013, from 8 a.m. to 5 p.m. This meeting is a reschedule of a postponed meeting announced in the **Federal Register** of June 8, 2012 (77 FR 34051–34052), originally scheduled for October 29–30, 2012.

ADDRESSES: FDA has opened a docket for public comment on this meeting. The docket number is FDA–2012–N–0548. The docket opened for public comment on June 8, 2012. The docket will close on February 1, 2013. Interested persons may submit either electronic or written comments regarding this meeting. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments received on or before January 9, 2013, will be provided to the committee before the meeting. Any comments received for the originally scheduled October 29 and 30, 2012, Drug Safety and Risk Management Advisory Committee meeting will be provided to the committee. It is not necessary to resubmit any comments previously submitted to the docket. If a comment originally submitted to the docket is resubmitted prior to January 9, 2013, both comments will be provided to the committee.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD, 20993–

0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *DSaRM@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On January 24 and 25, 2013, the committee will discuss the public health benefits and risks, including the potential for abuse, of drugs containing hydrocodone either combined with other analgesics or as an antitussive. The Department of Health and Human Services received a request from the Drug Enforcement Administration for a scientific and medical evaluation and scheduling recommendation for these products in response to continued reports of misuse, abuse, and addiction related to these products. The committee will also discuss the impact of rescheduling these hydrocodone products from Schedule III to Schedule II.

Background materials for the originally scheduled October 29–30, 2012, Drug Safety and Risk Management Advisory Committee meeting are currently available at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm307385.htm.* FDA intends to make background material available to the public no later than 2 business days before the January 24 and 25, 2013, Drug Safety and Risk Management Advisory Committee meeting at: *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. If FDA is unable to post background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and background material will be posted on FDA's Web site after the meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the docket (see the **ADDRESSES** section of this document) on or before January 9, 2013, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 10:15 a.m. on January 25, 2013. Those individuals interested in making formal oral presentations, including those who have previously requested time to speak at the originally scheduled October 29–30, 2012, Drug Safety and Risk Management Advisory Committee meeting, should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 3, 2013. Any individuals who requested time to speak at the originally scheduled October 29–30, 2012, Drug Safety and Risk Management Advisory Committee meeting, will need to follow the above instructions to request time to speak at the January 24–25, 2013, Drug Safety and Risk Management Advisory Committee meeting, as any previous requests to speak at the originally scheduled meeting do not convey to this new January 24–25, 2013, Drug Safety and Risk Management Advisory Committee meeting. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 4, 2013.

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

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristina Toliver at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: *December 10, 2012.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30517 Filed 12–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1172]

Impact of Approved Drug Labeling on Chronic Opioid Therapy; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain information, particularly scientific evidence, such as study data or peer-reviewed analyses, on issues pertaining to the use of opioid drugs in the treatment of chronic pain.

DATES: The public hearing will be held on February 7 and 8, 2013, from 9 a.m. to 4 p.m. Submit electronic or written requests to make oral presentations and comments by January 18, 2013. Electronic or written comments will be accepted after the hearing until April 8, 2013.

ADDRESSES: The public hearing will be held at the Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814, 301–897–9400, Fax 1–301–897–0192.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments 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. Transcripts of the hearing will be available for review at the Division of