

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Absenteeism guidance | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Notify FDA of Plan Activation and Deactivation | 2 | 1 | 2 | 16 | 32 |

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN ¹

| Absenteeism guidance | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|----------------------------|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| Develop Initial Plan | 70 | 1 | 70 | 500 | 35,000 |

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

Dated: November 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-28735 Filed 11-29-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0748]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups About Drug Products as Used by the Food and Drug Administration

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 January 2, 2014.

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 emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the

OMB control number 0910-0677. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, *PRAStaff@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.

Focus Groups About Drug Products as Used by the Food and Drug Administration—(OMB Control Number 0910-0677)—Extension

Focus groups provide an important role in gathering information because they allow for a more in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain information that is useful for developing variables and measures for quantitative studies,
- To better understand people's attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine its ideas and to help develop messages and other communications, but will generally conduct further research before making important decisions such as adopting

new policies and allocating or redirecting significant resources to support these policies.

FDA's Center for Drug Evaluation and Research, Office of the Commissioner, and any other Centers or Offices conducting focus groups about regulated drug products may need to conduct focus groups on a variety of subjects related to consumer, patient, or healthcare professional perceptions and use of drug products and related materials, including but not limited to:

- Direct-to-consumer prescription drug promotion,
- physician labeling of prescription drugs,
- Medication Guides,
- over-the-counter drug labeling,
- emerging risk communications,
- patient labeling,
- online sales of medical products, and
- consumer and professional education.

Annually, FDA projects about 20 focus group studies using 160 focus groups with an average of 9 persons per group, and lasting an average of 1.75 hours each. FDA is requesting this burden for unplanned focus groups so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of June 28, 2013 (78 FR 38993), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Focus Groups About Drug Products | 1,440 | 1 | 1,440 | 1.75 | 2,520 |

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

Dated: November 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28736 Filed 11–29–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel NIMH HIV/AIDS R34 Review.

Date: December 2, 2013.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Mental Health, Special Emphasis Panel, Mental Health Services 2.

Date: December 4, 2013.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 25, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–28727 Filed 11–29–13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4155–DR; Docket ID FEMA–2013–0001]

South Dakota; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of South Dakota (FEMA–4155–DR), dated November 8, 2013, and related determinations.

DATES: *Effective Date:* November 8, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated November 8, 2013, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency

Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the State of South Dakota resulting from a severe winter storm, snowstorm, and flooding during the period of October 3–16, 2013, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the State of South Dakota.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Disaster Unemployment Assistance and Public Assistance in the designated areas and Hazard Mitigation throughout the State. You are further authorized to provide snow assistance under the Public Assistance program for a limited time during or proximate to the incident period. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Gary R. Stanley, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of South Dakota have been designated as adversely affected by this major disaster:

Butte, Corson, Custer, Dewey, Fall River, Haakon, Harding, Jackson, Lawrence, Meade, Pennington, Perkins, Shannon, and Ziebach Counties and the Cheyenne River Sioux Tribe of the Cheyenne River Reservation within Dewey and Ziebach Counties and the Oglala Sioux Tribe within Jackson and Shannon