imposed by this regulation. The written agreement generally also includes contractual agreements that are a usual and customary business practice. The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the records required under the third-party disclosure section of this collection.

In the **Federal Register** of April 20, 2016 (81 FR 23309), 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 collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
Record retention, 801.150(a)(2)	90	20	1,800	.5	900

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (hours)	Total hours
Agreement and labeling requirements, 801.150(e)	90	20	1,800	4	7,200

Dated: July 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18299 Filed 8–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Delegation of Authorities

Notice is hereby given that I have delegated to the Commissioner of Food and Drugs (the Commissioner) those authorities vested in the Secretary of the Department of Health and Human Services under sections 1002; 1003; 1004; 1005(f); and 1006(b) and (d) of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), which relate to the functions of the Food and Drug Administration.

This authority may be re-delegated. This delegation will be exercised in accordance with the Department of Health and Human Services' applicable policies, procedures, guidelines, and regulations.

I ratify and affirm any actions taken by the Commissioner or the Commissioner's subordinates that involved the exercise of the authority delegated herein prior to the effective date of this delegation. This delegation was effective on November 17, 2015.

Dated: July 27, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–18417 Filed 8–2–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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 meeting.

The meeting 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID SBIR Phase II Clinical Trial Implementation (U44).

Date: August 30, 2016.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 3F100, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Lynn Rust, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G42A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5069, *lrust@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 28, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–18391 Filed 8–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

[Docket No. SAMHSA–2016–0002]

Request for Comment on Report Entitled: Advancing the Care of Pregnant and Parenting Women With Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: SAMHSA, Center for Substance Abuse Treatment (CSAT), in HHS announces the opening of a docket to obtain public comment on a report entitled: Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and their Infants: A Foundation for Clinical Guidance.

This report describes the formal process agreed on and followed under the guidance of the federal steering committee (FSC). It explains the RAND Corporation (RAND)/University of California Los Angeles (UCLA)

Appropriateness Method (RAM), justifies its adoption, and reports the outcomes of its application that will form the basis for the development of clinical guidance. This report will serve as the foundation for the development of clinical guidance to be used by providers caring for women with opioid use disorder and their infants.

DATES: *Comment Close Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. no later than 30 days after date of publication in the **Federal Register**.

ADDRESSES: You may submit comments identified by Docket No. [SAMHSA–2016–0002] by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Electronically:* You may submit electronic comments to: *samhsa.ppdaoram@samhsa.hhs.gov.*
- *By regular mail:* You may mail written comments to the following address ONLY: SAMHSA, CSAT, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Attn: Docket No. [SAMHSA–2016–0002]. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail.* You may send written comments to the following address ONLY: SAMHSA, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Attn: Docket No. [SAMHSA–2016–0002].
- *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period: For delivery in Rockville, MD: SAMHSA, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852. To deliver your comments to the Rockville address, call telephone number (240) 276–2700 in advance to schedule your delivery with one of our staff members.

Instructions: To avoid duplication, please submit only one copy of your comments by only one method. All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For access to the report or comments received, go to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Melinda Campopiano, MD, Medical Officer, SAMHSA, CSAT, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Email: *samhsa.ppdaoram@samhsa.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received by the deadline will be available for public inspection at the SAMHSA, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (240) 276–2700.

Background: SAMHSA led a federal steering committee in overseeing the application of the RAND/UCLA Appropriateness Method (RAM) to the available evidence concerning the optimal management of opioid use disorder for women who are pregnant or parenting and the management of their infants. After completion of the literature review, generation of the indications, and the expert panel RAM rating process—all described in this report—this report was generated for the purpose of producing a clinical guide that will be written to facilitate optimal management of pregnant and parenting women with opioid use disorder and their infants across disciplines and treatment settings. The guide will have a dual purpose: First, to serve as a tool that will increase provider willingness and confidence to manage pregnant and parenting women with opioid use disorder and their infants; and second to help assure the care provided this population optimizes the outcomes for both mother and infant.

The purpose of this effort is to produce a patient-centered guide to be used in a range of clinical settings. SAMHSA plans to organize the results described in this report around clinical scenarios and interventions consistent with the range of ways that women with opioid use disorder may access substance use treatment or maternity care. The guide will provide options for clinical interventions that recognize the complexities of patients' lives. The guide will also include discussion of any conflicting evidence and clinician, treatment or patient characteristics that directly influence the appropriateness or effectiveness of a given clinical intervention. The paucity of the evidence to support specific interventions will be addressed in the guide. As such, the guide will present options based on current clinical practice, paired with the risks and benefits of each option as currently understood.

Public comment is sought in two general areas: The outcomes of the RAM process and the strategy to translate these findings into a clinical guide. Relevant public comment will inform the development and final appearance of the guide. Members of the expert panel, FSC, and a variety of professional societies will be asked to provide input into the guide outline and drafting of the guide which will then be subject to a formal federal clearance process including scientific review.

Supporting and Related Material in the Docket: The report contains the materials to help inform public comment. The appendices include listings of participants, more detailed information about the literature search, citations of primary references and data tables that were used by SAMHSA to develop the findings in the report. The information provided includes:

(1) The REPORT.

(2) *Supporting appendices:* Appendix A: RAM Process Participants; Appendix B: Literature Review Methods; Appendix C: RAM Reference List and Appendices D–E7: Rated Indications.

Charles LoDico,

Chemist, SAMHSA/CSAP/DWP.

[FR Doc. 2016–18324 Filed 8–2–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1609]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports,