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**

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping (hours)</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record retention, 801.150(a)(2)</td>
<td>90</td>
<td>20</td>
<td>1,800</td>
<td>.5</td>
<td>900</td>
</tr>
</tbody>
</table>

**Table 2—Estimated Annual Third-Party Disclosure Burden**

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

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.

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/NIADD, 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)