

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1,2,3</sup>—Continued

Activity/21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual reports— 1002.13(a)–(b).	3628—General .....	1,466	1	1,466	18	26,388
	3634—TV .....					
	3638—Diagnostic x-ray .....					
	3641—Cabinet x-ray .....					
	3643—Microwave oven .....					
	3636—Laser .....					
	3631—Sunlamp .....					
	3647—Mercury vapor lamp .....					
	3645—Ultrasonic therapy .....					

<sup>1</sup> This table includes the recalculated burden estimate only for information collections (ICs) that are applicable to this draft guidance. It does not include all ICs approved under OMB control number 0910–0025. The draft guidance, if finalized, would be a reduction to the burden estimate for these ICs, except that the Abbreviated reports IC increases. We have described the overall reduction in the text of this document. However, to avoid confusion, we have not included a total burden estimate in this table because such a total would include ICs that are not applicable to the draft guidance.

<sup>2</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>3</sup> Totals may not sum due to rounding.

The draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073. The collections of information in 21 CFR parts 1002 through 1050 are approved under OMB control number 0910–0025.

Dated: July 28, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–18300 Filed 8–2–16; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2013–N–0375]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Agreement for Shipment of Devices for Sterilization**

**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 September 2, 2016.

**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 0910–0131. 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, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *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.

**Agreement for Shipment of Devices for Sterilization—21 CFR 801.150—OMB Control Number 0910–0131—Extension**

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for

sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms.

Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment, (2) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (3) specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (§ 801.150(a)(2)).

The respondents to this collection of information are device manufacturers and contract sterilizers. FDA’s estimate of the reporting burden is based on data obtained from industry over the past several years. It is estimated that each of the firms subject to this requirement prepares an average of 20 written agreements each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part-time basis for only one customer, while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements

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](mailto: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)