SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Cooperative Agreement to Support Navigators in Federally-facilitated and State Partnership Exchanges; *Use:* Section 1311(i) of the Affordable Care Act requires Exchanges (Marketplaces) to establish a Navigator grant program as part of its function to provide consumers with assistance when they need it. Navigators will assist consumers by providing education about and facilitating selection of qualified health plans (QHPs) within Marketplaces, as well as other required duties. Section 1311(i) requires that a Marketplace operating as of January 1, 2014, must establish a Navigator Program under which it awards grants to eligible individuals or entities who satisfy the requirements to be Exchange Navigators. For Federally-facilitated Marketplaces (FFMs) and State Partnership Marketplaces (SPMs), CMS will be awarding these grants. Navigator awardees must provide weekly, monthly, quarterly, and annual progress reports to CMS on the activities performed during the grant period and any sub-awardees receiving funds. CMS has modified the data collection requirements for the weekly, monthly, quarterly, and annual reports that were provided in 81 FR 29268 (May 11, 2016). *Form Number:* CMS–10463 (OMB control number: 0938–1215); *Frequency:* Annually; Quarterly; Monthly; Weekly; and Quarterly; *Affected Public:* Private sector; *Number of Respondents:* 102; *Total Annual Responses:* 102; 408; 1,224; 5,304; *Total Annual Hours:* 24,729. (For policy questions regarding this collection, contact Gian Johnson at 301–492–4323.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Issuer Reporting Requirements for Selecting a Cost-Sharing Reductions Reconciliation Methodology; *Use:* Sections 1402 and 1412 of the Affordable Care Act provide for reductions in cost sharing on essential health benefits for low- and moderate-income enrollees in silver level qualified health plans (QHP) on individual market Exchanges. It also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level. These cost-sharing reductions will help eligible individuals and families afford the out-of-pocket spending associated with health care services provided through Exchange-based QHP coverage.

The law directs QHP issuers to notify the Secretary of the Department of Health and Human Services (HHS) of cost-sharing reductions made under the statute for qualified individuals, and directs the Secretary to make periodic and timely payments to the QHP issuer equal to the value of those reductions. Further, the law permits advance payment of the cost-sharing reduction amounts to QHP issuers based upon amounts specified by the Secretary.

Under established HHS regulations, QHP issuers will receive advance payments of the cost-sharing reductions throughout the year. Each issuer will then be subject to one of two reconciliation processes after the year to ensure that HHS reimbursed each issuer the correct cost-sharing portion of advance payments. This information collection request establishes the data collection requirements for a QHP issuer to report to HHS which reconciliation reporting option the issuer will be subject to for a given benefit year. *Form Number:* CMS–10469 (OMB control number: 0938–1214); *Frequency:* Annually; *Affected Public:* Private sector (Businesses or other for-profits); *Number of Respondents:* 575; *Total Annual Responses:* 575; *Total Annual Hours:* 13,200. (For policy questions regarding this collection contact Pat Meisol at 410–786–1917.)

Dated: August 5, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–18986 Filed 8–9–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–1721; FDA–2012–N–0248; FDA–2011–N–0449; FDA–2012–N–0748; FDA–2012–N–0961; FDA–2012–N–0921; FDA–2014–N–0189; FDA–2004–N–0258]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Investigational New Drug Regulations	0910–0014	2/28/2019

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Guidance for Industry on Formal Dispute Resolutions; Appeals Above the Division Level	0910–0430	2/28/2019
SPF Labeling and Testing Requirements for OTC Sunscreen Products	0910–0717	2/28/2019
Generic Drug User Fee Cover Sheet—Form FDA 3794	0910–0727	2/28/2019
Environmental Impact Considerations	0910–0322	4/30/2019
FDA Adverse Event Reports; Electronic Submissions	0910–0645	5/31/2019
Importer's Entry Notice	0910–0046	6/30/2019
Exports: Notification and Recordkeeping Requirements	0910–0482	6/30/2019
Focused Mitigation Strategies to Protect Food Against Intentional Adulteration	0910–0812	6/30/2019

Dated: August 5, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–19021 Filed 8–9–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on October 5, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Jennifer Shepherd, 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, *AADPAC@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.

SUPPLEMENTARY INFORMATION:

Agenda: The committees will be asked to discuss naloxone products intended for use in the community, specifically the most appropriate dose or doses of naloxone to reverse the effects of life-threatening opioid overdose in all ages, and the role of having multiple doses available in this setting. The committees will also be asked to discuss the criteria prescribers will use to select the most appropriate dose in advance of an opioid overdose event and the labeling to inform this decision, if multiple doses are available.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the 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 the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 21, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations 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 September 13, 2016. 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 September 14, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Jennifer Shepherd 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).