The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the Agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: October 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25300 Filed 10–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0804]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification

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 November 27, 2013.

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 0910–0120. 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.

Premarket Notification—(OMB Control Number 0910–0120)—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) requires a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), product development protocol, humanitarian device exemption (HDE), petition for Evaluation of Automatic Class III Designation (de novo), or be reclassified into class I or class II before being marketed. FDA makes the final decision of whether a device is substantially equivalent or not equivalent.

Section 807.81 states when a premarket notification is required. A premarket notification is required to be submitted by a person who is:

(1) Introducing a device to the market for the first time;

(2) introducing a device into commercial distribution for the first time by a person who is required to register; and

(3) introducing or reintroducing a device which is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device.

Form FDA 3514, a summary cover sheet form, assists respondents in categorizing administrative 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational device exemptions, and HDEs. Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) as required by § 807.92 (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) with certain exceptions as per § 807.93 (510(k) statement). If the 510(k) submitter includes a 510(k) statement in the 510(k) submission, § 807.93 requires that the official correspondent of the firm make available within 30 days of a request all information included in the submitted premarket notification on safety and effectiveness. This information will be provided to any person within 30 days of a request if the device described in the 510(k) submission is determined to be substantially equivalent. The information provided will be a duplicate of the 510(k) submission including any safety and effectiveness information, but excluding all patient identifiers and trade secret and commercial confidential information.

Section 204 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115) amended section 514 of the FD&C Act (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including premarket notifications or other requirements. FDA has published and updated the list of recognized standards regularly since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87. Form FDA 3654, the 510(k) Standards Data Form, standardizes the format for submitting information on consensus standards that a 510(k) submitter chooses to use as a portion of their premarket notification submission (Form FDA 3654 is not for declarations of conformance to a recognized standard). FDA believes that use of this form will simplify the 510(k)

preparation and review process for 510(k).

Under § 807.90, submitters may request information on their 510(k) review status 90 days after the initial login date of the 510(k). Thereafter, the submitter may request status reports every 30 days following the initial status request. To obtain a 510(k) status report, the submitter should complete the status request form, Form FDA 3541, and fax it to the Center for Devices and Radiological Health office identified on the form.

The most likely respondents to this information collection will be specification developers and medical device manufacturers.

In the **Federal Register** of July 23, 2013 (78 FR 44130), 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 REPORTING BURDEN [1]

Activity/21 CFR part/Section/Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
510(k) submission (807 subpart E)	3,900	1	3,900	79	308,100
Summary cover sheet (807.87) and FDA 3514	1,956	1	1,956	0.5 (30 minutes)	978
Status request (807.90(a)(3)) and FDA 3541	218	1	218	0.25 (15 minutes)	55
Standards (807.87(d) and (f)); FDA 3654	2,700	1	2,700	10	27,000
510(k) summary and statement (807.92 and 807.93).	225	10	2,250	10	22,500
Total					358,633

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

Dated: October 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25298 Filed 10–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment; Notice of Meeting

In accordance with section l0(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following virtual committee meeting.

Name: CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

Dates and Times: November 13, 2013, 10:00 a.m.–4:30 p.m. November 14, 2013, 10:00 a.m.–12:30 p.m.

Place: This meeting is accessible via audio conference call and Adobe Connect Pro.

Status: This meeting is open to the public. The available lines will accommodate approximately 300 people.

Purpose: This Committee is charged with advising the Director, CDC, and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS, Viral Hepatitis and other STDs, the support of health care services to persons living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS, Viral Hepatitis, and other STDs.

Agenda: Agenda items include: (1) Affordable Care Act (ACA) Updates; (2) Clinical Workforce Issues; and (3) CHAC Workgroup Updates. Agenda items are subject to change as priorities dictate. To register for this event, please go to the following link: *https://hrsa.connectsolutions.com/advisorychac/event/registration.html.*

After you register, you should receive a confirmation email with a URL link for access to this event. You will also need to enter your Adobe Connect user name and password. If you've never used Adobe Connect, get a quick overview: *http://www.adobe.com/go/connectpro_overview.*

The public can join the meeting by:

1. (Audio Portion) Calling the Toll free Phone Number 1–888–324–9564 and providing the Participant Pass Code 4805129, and

2. (Visual Portion) Connecting to the Advisory Committee Adobe Connect Pro Meeting using the following URL: *https://hrsa.connectsolutions.com/advisorychac/event/login.html* (copy and paste the link into your browser if it does not work directly).

Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. Call (301) 443–9684 or send an email to *sgordon@hrsa.gov* if you are having trouble registering for this meeting; or call (301) 443–2843 or send an email to *lfores@hrsa.gov* if you are having trouble connecting to the meeting site.

Public Comment: Persons who desire to make an oral statement may request it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

FOR FURTHER INFORMATION CONTACT: Shelley B Gordon, Health Resources and Services Administration, HIV/AIDS Bureau, 5600 Fishers Lane, Rockville, Maryland 20857, telephone at (301) 443–9684.

Dated: October 21, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–25231 Filed 10–25–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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.