ADDRESSES: The meeting will be held at 200 Independence Ave. SW., Room 505A, Washington, DC 20201 on April 28, 2014. The meeting will take place via teleconference on April 29, 2014.

FOR FURTHER INFORMATION CONTACT: Office of the Surgeon General, 200 Independence Ave. SW., Washington, DC 20201; 202–205–9517; *prevention.council@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Group is a non-discretionary federal advisory committee that was initially established under Executive Order 13544, dated June 10, 2010, to comply with the statutes under Section 4001 of the Patient Protection and Affordable Care Act, Public Law 111–148. The Advisory Group was established to assist in carrying out the mission of the National Prevention, Health Promotion, and Public Health Council (the Council). The Advisory Group provides recommendations and advice to the Council.

The Advisory Group was terminated on September 30, 2012, by Executive Order 13591, dated November 23, 2011. Authority for the Advisory Group to be re-established was given under Executive Order 13631, dated December 7, 2012. Authority for the Advisory Group to continue to operate until September 30, 2015 was given under Executive Order 13652, dated September 30, 2013.

It is authorized for the Advisory Group to consist of not more than 25 non-federal members. The Advisory Group currently has 22 members who were appointed by the President. The membership includes a diverse group of licensed health professionals, including integrative health practitioners who have expertise in (1) worksite health promotion; (2) community services, including community health centers; (3) preventive medicine; (4) health coaching; (5) public health education; (6) geriatrics; and (7) rehabilitation medicine.

During this meeting, the Advisory Group will have round table discussions with representatives of Council member departments and develop recommendations for the Council for the upcoming year.

Members of the public who wish to attend the meeting on April 28, 2014 or to participate by phone in the April 29, 2014 meeting must register by 12:00 p.m. EST on April 21, 2014. Individuals should register for public attendance at *prevention.council@hhs.gov* by providing your full name and affiliation. Individuals who plan to attend the meeting and need special assistance and/or accommodations, i.e., sign language interpretation or other reasonable accommodations, should indicate so when they register. The public will have the opportunity to provide comments to the Advisory Group on April 28, 2014; public comment will be limited to 3 minutes per speaker. Registration via email (*prevention.council@hhs.gov*) is also required for the public comment session. Any member of the public who wishes to have printed materials distributed to the Advisory Group for this scheduled meeting should submit material to *prevention.council@hhs.gov* no later than 12:00 p.m. EST on April 21, 2014.

Dated: March 25, 2014.

Corinne M. Graffunder,

Designated Federal Officer, Advisory Group on Prevention, Health Promotion, and Integrative and Public Health, Office of the Surgeon General.

[FR Doc. 2014–07848 Filed 4–8–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0194]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump—Premarket Notification Submissions

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 May 9, 2014.

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–NEW and the title ''Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions.'' 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.

Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions—(OMB Control Number 0910–NEW)

This draft guidance is intended to assist industry in preparing premarket notification submissions for infusion pumps and to identify device features that manufactures should address throughout the total product life cycle. The draft guidance is available at (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm206153.htm*).

In the **Federal Register** of April 26, 2010 (75 FR 21632), FDA published a notice seeking comment on the proposed information collection activity. Given the lapse in time since its publication, FDA is reissuing this notice, responding to a single comment and providing the public an additional opportunity to comment on this proposed information collection activity, prior to the issuance of the final guidance document.

In the April 26, 2010, notice, FDA estimated it will receive 31 infusion pump submissions annually. The Agency reached this estimate by averaging the number of premarket notifications for infusion pumps submitted to FDA over the past 5 years. The draft guidance identifies 56 potential hazards FDA recommends addressing if applicable to a particular device. Although there may be additional hazards identified by a manufacturer, the Agency believes these hazards may offset FDA identified hazards not applicable to a particular device. FDA estimates it will take infusion pump manufactures approximately 56 hours (approximately 1 hour per hazard) to complete the case assurance report described in section 6 of the draft guidance. FDA reached this estimate based on its expectation of the amount of information that will be contained in the report.

However, based on a single public comment provided to FDA, related to the FDA burden estimate, we are

adjusting the burden associated with this collection. The public comment is summarized as follows: ''It will take significantly longer than one hour to conduct assurance case reports for each of the 56 potential hazards identified * * *. For instance, due to the iterative nature of the assurance case report process, each of the applicable hazards will need to be re-evaluated at multiple stages of the development process. In addition, it will be difficult to estimate the time required to conduct an assurance case report without specific guidance on the assurance case reports.''

While the commenter believes the reporting burden is greater than 1 hour, and FDA agrees, it is also important to note that the burden associated with this new recommendation to present data is the time and effort necessary to comply with submitting a new 510(k) or 510(k) supplements for legally marketed infusion pumps for which no assurance case exists. The Agency has revised the burden estimate, by averaging the number of premarket notifications for infusion pumps submitted to FDA over the past 5 years. The draft guidance identifies 56 potential hazards FDA recommends addressing if applicable to a particular device. Although there may be additional hazards identified by a manufacturer, the Agency believes the reporting of these hazards may be offset by FDA identified hazards not applicable to a particular device. FDA has revised the estimate of time it will take infusion pump manufactures from approximately 56 hours to 112 hours (approximately 2 hours per hazard) to submit the case assurance report described in section 6 of the draft guidance. FDA reached this estimate based on its expectation of the amount of information that will be contained in the report and the public comment received.

The respondents to this collection of information are infusion pump manufacturers subject to FDA's laws and regulations.

In the **Federal Register** of March 18, 2013 (78 FR 16676), FDA published a 60-day notice requesting public comment on the proposed collection of information to which two comments were received.

One commenter had created their own assurance case and used their results to assist in answering the 60-day notice. The commenter developed an Infusion Pump Assurance Case (IPAC) report template and conducted an informal survey of infusion pump manufacturers asking them to estimate the time and resources required to prepare their assurance case submissions in man months. Based on company responses, the average in man months for development of an assurance case was 12.83 man months. The highest response was 36 man months. Even with use of a least burdensome template similar to the IPAC, we would anticipate that the number of hours to prepare an assurance case submission would be significant. The commenter does not provide the methodology used in their estimate of man months, including details regarding the number of hours in a man month. Therefore, we decline to adjust our burden hour estimate at this time.

Another commenter estimates the time that it takes infusion pump manufacturers to complete an assurance case report is approximately 560 hours for a manufacturer with experience completing assurance case reports, which is substantially longer than FDA's estimate of approximately 112 hours. Increased knowledge and experience in creating assurance case reports has reduced the number of hours required, and the commenter estimates that this equates to approximately 10 hours needed for each of the 56 hazards identified in the draft guidance, or 560 hours allotted for an experienced team.

Though the commenter's assurance case was comprehensive, it included activities that should already be conducted under their existing design controls (e.g., gathering data from all aspects of product development and performing a cross-functional review). These activities are already covered under the Quality Systems ICR (OMB control number 0910–0073) and, to avoid double-counting the burden, should not be counted as burden in this information collection request.

FDA has been engaged over the past 2 years in the creation of an assurance case argument structures for use in the final infusion pump guidance and the Association for the Advancement of Medical Instrumentation Technical Information Reports. These are certainly time-intensive efforts. However, in our own experience, much of the effort is focused on correct and complete identification of hazards and effective mitigation strategies. Again, these activities, while used to support the bulk of the assurance case, are already required and should therefore not be counted as burden in this information collection request.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance Title: Infusion Pumps—Premarket Notification 510(k) Submissions	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Guidance Section 6—Assurance Case Report	31	1	31	112	3,472

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

Dated: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07915 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P