4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0194]

Agency Information Collection Activities; Proposed Collection; Comment Request; Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump--Premarket Notification [510(k)] Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on "Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump--Premarket Notification [510(k)] Submissions."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Daniel Gittleson,

Office of Information Management,

Food and Drug Administration,

1350 Piccard Dr.,

PI50-400B,

Rockville, MD 20850,

301-796-5156,

Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the 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. "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 provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper

performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump--Premarket Notification [510(k)] Submissions--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 March 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 and additional opportunity to comment on this proposed information collection activity, prior to the issuance of the final guidance document.

In the March 26, 2010, notice, the 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.

The Agency 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	No. of Respondents	No. 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.

The premarket notification procedures discussed in the draft guidance (21 CFR 807, subpart E) have been approved under OMB control number 0910-0120. The proposed information collection seeks to add clinical or scientific data demonstrating that new or changed infusion pumps are as safe and effective as those legally marketed and do not raise different questions of safety and effectiveness than predicate devices in this generic device type. In this way manufacturers of infusion pumps may demonstrate substantial equivalence and receive premarket clearance for their devices.

This draft guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 803 are approved under OMB control number 0910-0437; the collections of information in 21 CFR part 801 are approved under OMB control number 0910-0485; the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078; the collections of information in 21 CFR part

814, subparts B and E are approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910-0073; the collections of information in 21 CFR part 822 are under OMB control number 0910-0449; and the collections of information in 21 CFR 56.115 are approved under OMB control number 0910-0130.

Dated: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-06128 Filed 03/15/2013 at 8:45 am; Publication Date: 03/18/2013]