4160-01-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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump--Premarket Notification Submissions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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 All comments should be identified with the OMB control number 0910-NEW and the title "Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump--Premarket Notification [510(k)] Submissions."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Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump--Premarket Notification [510(k)] Submissions--(OMB Control Number 0910-NEW)

This draft guidance is intended to assist industry in preparing premarket notification submissions for infusion pumps and to identify device features that manufactures should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 The draft guidance is available at (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm206153.htm).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

Dated: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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