4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0041]

Agency Information Collection Activities; Proposed Collection; Comment Request; Safety Assurance Case; Withdrawal of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a notice that was published in the *Federal Register* of March 15, 2017.

DATES: [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of March 15, 2017 (82 FR 13817), "Agency Information Collection Activities; Proposed Collection; Comment Request; Safety Assurance Case," FDA requested comment on the information collection associated with safety assurance cases (SACs).

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

In the March 15, 2017, *Federal Register* notice, FDA proposed to extend the information collection related to SACs (OMB control number 0910-0766). However, we are withdrawing the notice because, upon further review of the information collection request (ICR) associated with the notice and comments received on the information collection, we have determined that the estimated burden expressed in the SAC ICR is included as part of the estimated burden for the information collections in the premarket notification (510(k)) ICR (OMB control number 0910-0120).

Because the information collected for safety assurance cases is already included under another information collection approval, we have discontinued the ICR and we are withdrawing the March 15, 2017, notice requesting comment on the information collection.

The guidance entitled "Infusion Pumps Total Product Life Cycle; Guidance for Industry and FDA Staff" (*https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm209337.pdf*), which provides recommendations on the inclusion of safety assurance cases as part of the premarket submissions for new, changed, or modified infusion pumps submitted by device manufacturers, continues to provide the Agency's current thinking on this topic.

Dated: August 2, 2017.

Anna K. Abram,

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

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