

regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 1, 2017.

Anna K. Abram,

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

[FR Doc. 2017–16516 Filed 8–4–17; 8:45 am]

BILLING CODE 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: August 7, 2017.

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, PRASStaff@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.

[FR Doc. 2017–16561 Filed 8–4–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Final Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of final product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new

drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site. The product-specific guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for “Product-Specific