4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-D-0039 (Formerly 2006D-0408)]

Annual Reports for Approved Premarket Approval Applications, Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Annual Reports for Approved Premarket Approval Applications (PMA)." The purpose of this guidance is to describe the information required to be included in an annual report for an approved PMA, additional information requirements that may be imposed by an approval order, and FDA's recommendations for the level of detail the applicant should provide in the annual report. It also identifies the steps FDA staff generally takes when reviewing annual reports, the resources available to assist staff in their reviews, and the regulatory actions they may recommend after reviewing annual reports.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Annual Reports for Approved Premarket Approval Applications (PMA)" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug

Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

I. Background

In the Federal Register of October 26, 2006 (71 FR 62595), FDA announced the availability of its draft guidance entitled, "Annual Reports for Approved Premarket Approval Applications (PMA)," and invited interested persons to comment on the document. FDA received several comments, most of which sought additional clarification and recommendations about the level of detail and format of annual reports. We considered all of the comments received and revised the guidance where appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on annual reports for

PMAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all Center for Device and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov or from the Center for Biologics Evaluation and Research (CBER) at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. To receive "Annual Reports for Approved Premarket Approval Applications (PMA)," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1585 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR 814.82(a)(7) and 814.84(b) have been approved under OMB control number 0910-0231.

Under section 3506(c)(2)(A) of the PRA, FDA provided a 60-day notice concerning the proposed collection of information set forth in the draft guidance (71 FR 62595, October 26,

2006). In response to the notice, FDA received several comments pertaining to the information collection.

Comments noted that for changes previously submitted in a regulatory submission, requiring a rationale for each change is burdensome and duplicative because FDA already has this information. In response to this comment, FDA modified the guidance to request only limited information for changes that were submitted as either a PMA supplement or 30-day notice, including supplement number and the status of the document.

Comments requested clarification of the type of information, data, and level of detail that need to be provided. In response, FDA removed columns from the proposed "Changes Table" in the guidance, including columns for validation testing, implementation date, approval date, and risk analysis.

As a result of modifications made to the guidance in response to comments, the guidance no longer imposes an information collection burden additional to that previously approved in OMB control number 0910-0231. FDA is therefore no longer requesting approval of an additional information collection.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is necessary to send only one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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