4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0524]

Draft Guidance for Industry and Food and Drug Administration Staff; Acceptance and Filing Review for Premarket Approval Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Acceptance and Filing Review for Premarket Approval Applications (PMAs)." The purpose of the acceptance and filing reviews is to make a threshold determination about whether an application is administratively complete. This guidance document is intended to clarify the criteria for accepting and filing a PMA, thereby assuring the consistency of our acceptance and filing decisions. This guidance is applicable to original PMAs and PMA panel-track supplements reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Acceptance and Filing Review for Premarket Approval Applications (PMAs)" to the Division of Small Manufacturers, International and Consumer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 Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, 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Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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I. Background

The PMA regulation (21 CFR 814.42(e)) identifies the criteria that, if not met, may serve as a basis for refusing to file a PMA. These criteria are discussed in the guidance document "Guidance for Industry and FDA Staff Premarket Approval Application Filing Review," dated May 1, 2003. This document has been used by FDA staff and the device industry to help elucidate the broad preclinical and clinical issues that need to be addressed in a PMA and the key decisions to be made during the filing process.

To further focus the Agency's review resources on complete applications, which will provide a more efficient approach to ensuring that devices that have a reasonable assurance of safety and effectiveness reach patients as quickly as possible, we have modified the PMA filing guidance. In this guidance entitled, "Acceptance and Filing Review for Premarket Approval Applications (PMAs)," we have separated the requirements for PMA filing into: (1) Acceptance criteria and (2) filing criteria. Acceptance review involves an early assessment of the completeness of the application, and informing the applicant in a written response within the first 15 calendar days of receipt of the application whether any administrative elements are missing, and if so, identifying the missing administrative element(s).

In order to enhance the consistency of our acceptance and filing decisions and to help applicants understand the types of information FDA needs to conduct a substantive review of a PMA, this guidance and associated checklist clarify the necessary elements and contents of a complete PMA application. The process we outline is applicable to all devices reviewed in a PMA application. Acceptance and filing decisions will be made for all original PMA applications and panel-track PMA supplements.

This guidance is not significantly different from the 2003 PMA guidance document. The "preliminary questions" remain the same and the "filing review questions" have been separated into "acceptance decision questions" (i.e., is the file administratively complete) and "filing decision questions" (i.e., are data consistent with the protocol, final device design, and proposed indications). In addition, it should be noted that this document is focused on the regulatory and scientific criteria for making an "Accept" or "Refuse to Accept" decision as well as "File" or "Not File" decision for a PMA. It specifically does not alter the following administrative aspects of the PMA filing process: The timeframe for the filing review phase (i.e., 45 days); the processes for document tracking, distribution, and handling; and the procedures for assembling the review team and setting up the filing meeting.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on acceptance and filing reviews 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. To receive "Acceptance and Filing Review for Premarket Approval Applications (PMAs)," 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 1792 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently 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 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send 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.

Dated: July 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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