

review. It was suggested that FDA identify a particular location within the submission for this information, noting that such information could be found in multiple locations. The guidance has been revised to suggest more specific locations within the submission where this information can be provided for the ease of compiling a 510(k) and to facilitate FDA staff's acceptance review.

Other comments provided editorial suggestions for clarity and for consistency with other FDA guidance documents. In response to these comments, FDA revised the guidance document to clarify the processes and policies as appropriate. This guidance supersedes the guidances "Center for Devices and Radiological Health's Premarket Notification (510(k)) Refuse to Accept Policy" issued on June 30, 1993 and "510(k) Refuse to Accept Procedures, 510(k) Memorandum K94-1" issued on May 20, 1994.

## 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 the refuse to accept policy for 510(k)s. 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 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 "Refuse to Accept Policy for 510(k)s," you may either send an email request to [dsmica@fda.hhs.gov](mailto: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 1793 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This 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 807, subpart E, have been

approved under OMB control number 0910-0120.

## 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 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 26, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Guidance for Industry and Food and Drug Administration Staff; Acceptance and Filing Reviews 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 guidance entitled "Acceptance and Filing Reviews 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 (CBER).

**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 "Acceptance and Filing Reviews 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 (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

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. The guidance entitled "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)" supersedes the guidance entitled "Guidance for Industry and FDA Staff Premarket Approval Application Filing Review."

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 Reviews 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 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: (1) The time frame for the filing review phase (i.e., 45 days); (2) the processes for document tracking, distribution, and handling; and (3) the procedures for assembling the review team and setting up the filing meeting.

In the **Federal Register** of July 31, 2012 (77 FR 45357), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by September 14, 2012. Nine comments were received with multiple recommendations pertaining to the administrative processes and policies regarding acceptance and filing review decisions. In response to these comments, FDA revised the guidance document to clarify the processes and policies as appropriate. This guidance supersedes

the guidance entitled "Guidance for Industry and FDA Staff Premarket Approval Application Filing Review," dated May 1, 2003.

## 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 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 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> or from the CBER internet site at <http://www.fda.gov/BiologicsBloodVaccines/RegulatoryInformation/default.htm>. To receive "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)," you may either send an email request to [dsmica@fda.hhs.gov](mailto: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 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 either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 26, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-1056]

### Guidance for Industry and Food and Drug Administration Staff; eCopy Program for Medical Device Submissions; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "eCopy Program for Medical Device Submissions." The purpose of the guidance is to explain the new electronic copy (eCopy) Program for medical device submissions, which is intended to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version. The guidance describes how FDA has implemented the eCopy Program under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This guidance also provides the standards for a valid eCopy under the FD&C Act and identifies the submission types that must include an eCopy in accordance with these standards for the submission to be processed and accepted for review by FDA. This final guidance will be considered in effect on January 1, 2013, or at the time of publication, whichever is later.

**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 "eCopy Program for Medical Device Submissions" 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. Send