

Dated: December 19, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0523]

Guidance for Industry and Food and Drug Administration Staff; Refuse To Accept Policy for 510(k)s; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Refuse to Accept Policy for 510(k)s.” The purpose of this document is to explain the procedures and criteria FDA intends to use in determining whether a 510(k) submission is administratively complete, which determines whether it should be accepted for substantive review and clearance. This guidance is applicable to 510(k)s 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 “Refuse to Accept Policy for 510(k)s” 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:

Geeta Pamidimukkala, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1564, Silver Spring, MD 20993-0002, 301-796-6453; 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.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the 510(k) acceptance review is to make a threshold determination whether a submission is administratively complete, which determines whether it should be accepted for substantive review to reach a determination regarding substantial equivalence under section 513(i) of the FD&C Act, 21 U.S.C. 360c(i). To find a device substantially equivalent under section 513(i) of the FD&C Act, FDA must find that it has the same intended use as the predicate device, and either: (1) Has the same technological characteristics as the predicate device, or (2) has different technological characteristics, as defined at section 513(i)(1)(B), and (3) the submission contains information, including appropriate clinical or scientific data if necessary, that demonstrates the device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness from the predicate.

The purpose of this document is to explain the procedures and criteria FDA intends to use in determining whether a 510(k) submission is administratively complete and should be accepted for substantive review. This guidance document provides updated information to two existing guidance documents entitled “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. Upon issuance as a final guidance document, this guidance will replace those documents.

To further focus the Agency’s review resources on complete applications, which will provide a more efficient approach to ensuring that safe and effective medical devices reach patients

as quickly as possible, we have modified the 1993 and 1994 guidances. For example, we have modified the 510(k) Refuse to Accept (RTA) policy to include an early review against specific acceptance criteria and to inform the submitter within the first 15 calendar days of receipt of the submission if the submission is administratively complete, or if not, to identify the missing element(s). In order to enhance the consistency of our acceptance decisions and to help submitters better understand the types of information FDA needs to conduct a substantive review, this guidance, including the checklists included in the appendices, clarifies the necessary elements and contents of a complete 510(k) submission. These elements are applicable to all devices reviewed through the 510(k) notification process in CDRH and CBER and have been compiled into checklists for use by FDA review staff.

In the **Federal Register** of August 13, 2012 (77 FR 48159), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by September 27, 2012. Eleven sets of comments were received with multiple recommendations pertaining to the administrative processes and policies regarding 510(k) acceptance decisions.

A number of commenters expressed concern that the checklist questions related to performance data implied that FDA staff would need to conduct a level of substantive review in order to complete the checklist. FDA has revised the language in these questions and added further instructions to FDA staff to more specifically state that only the presence of the information is required for acceptance, and that the adequacy of the information should only be assessed after acceptance and as part of the substantive review.

Similar comments were received regarding questions in the checklists that identified an “analysis” or “discussion” as a criterion for acceptance. Commenters were concerned that FDA staff would be assessing the adequacy of the “analysis” or “discussion” in order to complete the checklist. These questions have also been modified to explain more clearly that the acceptance criterion requires only that the “analysis” or “discussion” be present; the adequacy of this information should be assessed during the substantive review.

FDA received comments regarding relevant prior submissions and how prior FDA feedback relevant to determining substantial equivalence has been addressed in the submission under

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 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