4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry and Food and Drug Administration Staff; Refuse to Accept Policy for 510(k)s; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Refuse to Accept Policy for 510(k)s." The purpose of this document is to explain the procedures and criteria FDA intends to use in determining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 premarket notification (510(k)) submission is administratively complete, which determines whether it should be accepted for substantive review. 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). This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Refuse to Accept Policy for 510(k)s" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and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, 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Submit electronic comments on the draft guidance to http://www.regulations.gov.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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301-796-6453;

or

Stephen Ripley,

Center for Biologics Evaluation and Research (HFM-17),

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301-827-6210.

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 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 than 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 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.

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 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 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.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm or 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 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 807, subpart E, have been approved under OMB control number 0910-0120.

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: August 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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