4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0900]

Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics." This guidance is intended to provide greater clarity regarding the principal benefit-risk factors that FDA considers during the review process for a premarket notification (510(k)) submission when there are different technological characteristics between the new device and the legally marketed (predicate) device. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled " Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Office of Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993-0002, 301-796-5900, or, Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

A submitter of a premarket notification submission (510(k)) must demonstrate to FDA in its 510(k) submission that the new device is "substantially equivalent" to a "predicate device" (see section 513(i) of the Federal Food, Drug & Cosmetic Act (21 U.S.C. § 360c(i)). At certain points in the substantial equivalence analysis, the probable benefits and risks of a new device as compared to a legally marketed (predicate) device may be relevant. This draft guidance does not focus on benefit-risk factors that may be considered during the first step of the 510(k) review process where FDA must find that the intended use of the device and the predicate device are "the same." Instead, this guidance focuses on the step of the 510(k) review process after FDA has determined that there are different technological characteristics between the new device and the predicate device, and FDA has determined that the differences in the technological characteristics do not raise different questions of safety and effectiveness. At this step in the review process, FDA must determine whether the new device is "as safe and effective" as the predicate device. This draft guidance discusses the principal benefit-risk factors FDA considers when making this determination, and also provides examples of how these factors may be used during premarket review.

The benefit-risk factors discussed in this guidance may assist FDA reviewers in making substantial equivalence determinations and may help accommodate evolving technology during the 510(k) premarket process. This guidance may also help submitters of 510(k) premarket notifications demonstrate substantial equivalence in their premarket submissions. FDA has developed this guidance in order to improve the predictability, consistency, and transparency of the 510(k) premarket review process. This guidance does not change the 510(k) premarket review standard or create extra burden on a

submitter of a 510(k) to provide additional performance data from what has traditionally been submitted during the review process for 510(k) submissions.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the Agency's current thinking on benefit-risk factors to consider when determining substantial equivalence in medical device premarket notifications (510(k)) with different technological characteristics. 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 http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. Persons unable to download an electronic copy of "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics," may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1818 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The 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; and the collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). 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: July 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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