4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0577]

Guidance for Industry and Food and Drug Administration Staff; Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications." This guidance is intended to provide greater clarity on FDA's decisionmaking process with regard to benefit-risk determinations in the premarket review of medical devices in the premarket approval and de novo pathways.

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 "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development (HFM-40), Center for

Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist 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:

For devices regulated by CDRH:

Ruth Fischer,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 4424,

Silver Spring, MD 20993-0002,

301-796-5735.

For devices regulated by CBER:

Stephen Ripley,

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

Food and Drug Administration,

1401 Rockville Pike,

Suite 200N,

Rockville, MD 20852,

301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

There are many factors that go into assessing the probable benefit of a device versus its probable risk. This guidance sets out the principal factors FDA considers when making this determination and explains them in detail. This guidance also gives examples of how the factors interrelate and how they may affect FDA's decisions. By clarifying FDA's decisionmaking process in this way, we hope to improve the predictability, consistency, and transparency of the review process for applicable devices. The factors described in this guidance apply to devices submitted under premarket approval applications and de novo petitions.

This guidance also includes a worksheet that reviewers will use in making benefit-risk determinations for applicable devices. The worksheet is attached as Appendix B to the guidance, and examples of how reviewers might use the worksheet are attached as Appendix C to the guidance. This level of documentation is very helpful to maintaining the consistency of review across the different review divisions and better assuring that an appropriate decision is reached.

In the Federal Register of August 15, 2011 (76 FR 50483), FDA announced the availability of the draft guidance. Interested persons were invited to comment by November 14, 2011. FDA considered the comments and revised the guidance, as appropriate.

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 factors to consider when making benefit-risk determinations in medical device premarket approval and de novo

classifications. 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 is available for all CDRH guidance documents at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at either http://www.regulations.gov or http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. To receive "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications" from CDRH, 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 1772 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no new collections of information. The 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 814 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: March 22, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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