



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0363]

Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions; 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 or the Agency) is announcing the availability of the guidance entitled “Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions.” This guidance outlines FDA’s new, voluntary program for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions and that are subject to premarket approval (PMA) applications or de novo classifications. FDA believes that the Expedited Access Pathway (EAP) program will help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standard of reasonable assurance of safety and effectiveness for premarket approval, consistent with the Agency’s mission to protect and promote public health. The document also discusses how the

EAP program approaches the balance of premarket and postmarket data collection and incorporates a benefit-risk framework. The EAP program will become effective April 15, 2015.

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: 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 “Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions” 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 to 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 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: Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5449, Silver Spring, MD 20993-0002, 301-796-5178; or Stephen Ripley, Center for Biologics

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's EAP program contains features from the Center for Devices and Radiological Health's (CDRH's) Innovation Pathway, piloted in 2011 to facilitate the development and expedite the review of breakthrough technologies. In addition, the EAP program is based in part on FDA's experience with the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research programs that are intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions ("FDA drug-expedited programs"). However, while the EAP program incorporates some features of the FDA drug-expedited programs, it is a separate and distinct program tailored to devices and intended to further speed the availability of certain safe and effective devices that address unmet public health needs.

As part of the EAP program, FDA intends to provide more interactive communications during device development and more interactive review of Investigational Device Exemption applications, PMA applications, and requests for de novo review. This includes working with the sponsor to create a data development plan specific to the device, which would outline all data the sponsor intends to collect in support of device approval, and identifying what data would be collected premarket and postmarket. In addition, FDA intends to work interactively with the sponsor within the benefit-risk framework discussed in the FDA guidance, "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications," issued on March 28, 2012, and in accordance with statutory and

regulatory requirements, to determine whether certain data may be collected in the postmarket setting rather than in the premarket setting for devices subject to PMAs. This guidance details the EAP process, which will only be utilized at the request of the sponsor and with FDA's agreement.

At the time of this document's publication, FDA does not know whether the EAP program will require a significant increase in resources. FDA will devote as many resources to EAP as possible without adversely impacting our ability to meet our Medical Device User Fee Act commitments. Our experience with the Innovation Pathway showed that early and more extensive interactions with sponsors can consume a significant amount of manager and staff time. FDA plans to closely monitor implementation of EAP to determine whether we have sufficient resources to effectively implement the program.

A draft of this guidance was made available in the Federal Register on April 23, 2014, and the comment period closed July 22, 2014. Changes between the draft and final versions of this guidance include expanding the scope to include de novo requests, an increased focus on patient benefits, a clarification of how FDA will allocate resources to the EAP program, and a clarified explanation of the EAP designation process. FDA also provided more examples to help industry better understand in which cases EAP may be the most appropriate pathway to device approval. The final guidance also recognizes the potential for use of registry data to satisfy post-approval study requirements and adds an evaluation mechanism for the EAP program.

The EAP program will become effective April 15, 2015.

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 Expedited

Access PMA program. 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 downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at

[http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

[t.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm). Guidance documents are also available at <http://www.regulations.gov/> or from CBER at

[http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm)

[t.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm). Persons unable to download an electronic copy of “Expedited Access for Premarket

Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or

Irreversibly Debilitating Diseases or Conditions” may send an email request to [CDRH-](mailto:CDRH-Guidance@fda.hhs.gov)

[Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document

number 1400007 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously 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 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910-0332; the collections of

information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910-0449; and the collections of information regarding “Requests for Feedback on Medical Device Submissions” have been approved under OMB control number 0910-0756.

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 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: April 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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