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

FDA has long applied postmarket controls as a way to reduce premarket data collection, where appropriate, while assuring that the statutory standard for approval of reasonable assurance of safety and effectiveness is still met. The right balance of premarket and postmarket data collection facilitates timely patient access to important new technology without undermining patient safety.

In this draft guidance, FDA describes existing statutory requirements under the Federal Food, Drug, and Cosmetic Act, its implementing regulations, and FDA policies that support the policy on balancing premarket and postmarket data collection during review of PMA applications. In addition, FDA clarifies how the Agency considers postmarket data as part of the benefit-risk framework described in FDA's guidance ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications,'' issued on March 28, 2012. This guidance provides a resource for industry and FDA staff on how FDA determines when it is appropriate for a sponsor of a PMA to collect some data (clinical or non-clinical) in the postmarket setting, rather than premarket.

Elsewhere in this issue of the **Federal Register,** FDA is announcing another draft guidance entitled ''Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions,'' which also addresses the role of postmarket data and the benefit-risk framework as key elements of FDA's proposed ''Expedited Access Program.''

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on balancing premarket and postmarket data collection for devices subject to premarket approval. 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health 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 ''Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1833 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0449.

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 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09190 Filed 4–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0363]

Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Disease or Conditions; 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 or the Agency) is announcing the availability of the draft guidance entitled ''Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Disease or Conditions.'' This draft guidance outlines FDA's proposal for a 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 are subject to premarket approval applications (PMA). FDA believes that the Expedited Access PMA (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. 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 July 22, 2014.

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 draft guidance document entitled ''Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for

Life Threatening or Irreversibly Debilitating Disease 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 the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. 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 the Center Director, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993–0002, 301–796–5900; 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

FDA's proposed EAP program contains features from CDRH's Innovation Pathway, piloted in 2011 to facilitate the development and expedite the review of breakthrough technologies. In addition, the proposed 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 and PMA applications. 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 postmarket rather than premarket. This guidance details the EAP process which will only be utilized at the request of the sponsor and with FDA's agreement.

Elsewhere in this issue of the **Federal Register**, FDA is announcing another draft guidance entitled ''Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval,'' which also addresses the role of postmarket data and the benefit-risk framework to support premarket approval, while still meeting the statutory standard of reasonable assurance of safety and effectiveness.

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 expedited access for premarket approval medical devices intended for unmet medical need for life threatening or irreversibly debilitating diseases or conditions. 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 downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health 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 ''Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Disease or Conditions,'' may send an email request to *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

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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 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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