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In this draft guidance, FDA describes existing statutory requirements under the Federal Food, Drug, and Cosmetic Act, its implementing regulations, and FDA policies that support the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 nonclinical) 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Elsewhere in this issue of the Federal Register, FDA is announcing another draft guidance entitled “Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Disease or Conditions.” The Agency recently released a document, “Electronic Access to Premarket Approval Medical Devices Subject to Premarket Data Collection for Devices Subject to Premarket Approval,” 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This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on balancing premarket and postmarket data collection for devices subject to premarket approval.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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet.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/GuidanceCompliance RegulatoryInformation/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 0910–0073; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 820 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 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0231; 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.
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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:

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/AboutFDA/CentersOffices/CDRH/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

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.

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Leslie Kux,
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