



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5966]

Breakthrough Devices Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Breakthrough Devices Program; Draft Guidance for Industry and Food and Drug Administration Staff.” This guidance document describes policies that FDA intends to use to implement the new Breakthrough Devices Program, established by the 21st Century Cures Act (Cures Act). The Breakthrough Devices Program supersedes and combines elements from FDA’s Expedited Access Pathway (EAP), which was intended to facilitate the development and expedite review of breakthrough technologies, as well as the Priority Review Program, which implemented statutory criteria for granting priority review to premarket approval applications (PMAs) and applied those criteria to other types of premarket submissions for medical devices. This draft guidance clarifies certain principles and features of the new program, the designation criteria for Breakthrough Devices, the designation request review process, the process for withdrawing from the program, as well as the recommended information device manufacturers should provide in their designation request for entrance into the program. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2017-D-5966 for “Breakthrough Devices Program; Draft Guidance for Industry and Food and Drug Administration Staff.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 “Breakthrough Devices Program; Draft Guidance for Industry and Food and Drug Administration Staff” 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.

FOR FURTHER INFORMATION CONTACT: Erin Cutts, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1625, Silver Spring, MD 20993-0002, 301-796-6307; 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, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance to describe policies that FDA intends to use to implement section 515B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e-3, as created by section 3051 of the Cures Act (Pub. L. 114-255) and section 901 of the FDA Reauthorization Act of 2017 (Pub. L. 115-52) (the “Breakthrough Devices Program”). The Breakthrough Devices Program is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. This program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, clearance of a premarket notification (510(k)), and marketing authorization via the De Novo classification process, consistent with the Agency’s statutory mission to protect and promote public health. No later than 1 year after the date of enactment of the Cures Act, FDA is required to issue this draft guidance, which sets forth the process by which a person may seek a Breakthrough Device designation, provides a template for designation requests, identifies the criteria that FDA will use in evaluating designation requests, and identifies the criteria and processes FDA will use to assign and train a team of staff to review breakthrough devices after designation has been granted. See section 515B(f) of the FD&C Act.

As part of the Breakthrough Devices Program, FDA intends to provide interactive and timely communication with the sponsor during development and throughout the review process for devices designated as Breakthrough Devices under section 515B(d)(1) of the FD&C Act and grant priority to the review of associated Q-submissions, investigational device exemption (IDE) applications, PMAs, De Novo classification requests, and premarket notifications (510(k)s). In addition, for Breakthrough Devices subject to PMA, FDA may consider the amount of data that may be collected in the postmarket setting, rather than premarket, and the level of acceptable uncertainty in the benefit-risk profile at the time of approval. Getting the right balance between premarket and postmarket data collection--specifically, where appropriate, a greater reliance on postmarket collection--can reduce the extent of premarket data submission. Collectively, these and the other principles of the program described in this draft guidance are intended to support a least-burdensome approach for expediting patient access to Breakthrough Devices.

The Breakthrough Devices Program supersedes the EAP, which launched in 2015. The Breakthrough Devices Program contains features of the EAP as well as the Innovation Pathway (first piloted in 2011), both of which were intended to facilitate the development and expedite the review of breakthrough technologies.

The Breakthrough Devices Program also supersedes the Priority Review Program, which implemented statutory criteria for granting priority review to PMA submissions for medical devices, applied those criteria to other types of premarket submissions for medical devices, and included standard procedures to achieve an efficient priority review process.

## 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 current

thinking of FDA on “Breakthrough Devices Program; Draft Guidance for Industry and Food and Drug Administration Staff.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

### 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 <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <https://www.regulations.gov>. Persons unable to download an electronic copy of “Breakthrough Devices Program” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto: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 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 807, subpart E have been approved under OMB control number 0910-0120; the collections of information for De Novo classification requests have been approved under OMB control number 0910-0844; 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.

Dated: October 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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