

Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.” 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information for applicants required to submit ASRs on PMCs and PMRs under section 506B of the FD&C Act and the implementing regulations at §§ 314.81(b)(2)(vii) and 601.70 are approved under OMB control numbers 0910–0001 and 0910–0338, respectively.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20014 Filed 9–14–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5966]

Breakthrough Devices Program; 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 a final guidance entitled “Breakthrough Devices Program.” This final guidance describes policies that FDA intends to use to implement a section of the

Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance updates the previous version of the guidance, of the same title, issued on December 18, 2018, and describes how the Breakthrough Devices Program may also be applicable to certain devices that benefit populations impacted by health and/or healthcare disparities. Consistent with our obligations under the SUPPORT for Patients and Communities Act (SUPPORT Act), the Breakthrough Devices Program may be available for certain non-addictive medical products to treat pain or addiction.

DATES: The announcement of the guidance is published in the **Federal Register** on September 15, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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.” 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, 240–402–7500.

- **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.govinfo.gov/content/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, 240–402–7500.

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 guidance document entitled “Breakthrough Devices Program” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Ouided Rouabhi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G221, Silver Spring, MD 20993–0002, 240–402–2672; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance entitled “Breakthrough Devices Program.” The document describes policies that FDA intends to use to implement section 515B of the FD&C Act (21 U.S.C. 360e–3), as created by section 3051 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255), amended by section 901 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), and amended by section 3001 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271) (the “Breakthrough Devices Program”). The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is available for devices and device-led combination products that are subject to review under a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request (“De Novo request”).

The Breakthrough Devices Program may also be applicable to certain devices that benefit populations impacted by health and/or healthcare disparities, thereby promoting and advancing health equity. In addition, consistent with our obligations under section 3001 of the SUPPORT Act, the Breakthrough Devices Program may be available for certain non-addictive medical products to treat pain or addiction (section 515B of the FD&C Act). The considerations set forth in the guidance document apply to FDA’s review of devices as non-addictive methods to treat pain or addiction. This program is intended to help patients have more timely access to designated medical devices, including those that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions in populations impacted by health and/or healthcare disparities, by expediting their development, assessment, and review, while preserving the statutory standards for PMAs, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency’s mission to protect and promote public health.

This guidance finalizes the draft guidance entitled “Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Healthcare.” A notice of availability of the draft guidance appeared in the **Federal Register** of October 21, 2022 (87 FR 64057). FDA considered comments received and revised the guidance as appropriate in response to comments, including further clarifying FDA’s intent to consider technologies and device features that may help to address health and/or healthcare disparities and promote health equity by providing for more effective treatment or diagnosis in various populations that exhibit health and healthcare disparities. FDA did not substantively change the sections of the existing Breakthrough Devices Program guidance that were not affected by the select update.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the “Breakthrough Devices Program.” 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.

II. 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 Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Breakthrough Guidance Program” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00001833 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions	0910–0756
822	Postmarket Surveillance of Medical Devices	0910–0449
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Dated: September 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20007 Filed 9–14–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0109]

Fostering Medical Device Improvement: Food and Drug Administration Activities and Engagement With the Voluntary Improvement Program; 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 a final guidance entitled “Fostering Medical Device Improvement: Food and Drug Administration Activities and Engagement with the Voluntary Improvement Program.” FDA is issuing this guidance to describe its policy regarding FDA’s participation in the Voluntary Improvement Program (VIP). The VIP is a voluntary program facilitated through the Medical Device Innovation Consortium (MDIC) that evaluates the capability and performance of a medical device manufacturer’s practices using third-party appraisals, and is intended to guide improvement to enhance the quality of devices. The VIP builds on the framework piloted through FDA’s 2018 Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program (CfQ Pilot Program) and incorporates some of the successes and learnings from the pilot.

DATES: The announcement of the guidance is published in the **Federal Register** on September 15, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

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- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://](https://www.regulations.gov)

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–2022–D–0109 for “Fostering Medical Device Improvement: Food and Drug Administration Activities and Engagement with the Voluntary Improvement Program.” 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, 240–402–7500.

- *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.govinfo.gov/content/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, 240–402–7500. 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 guidance document entitled “Fostering Medical Device Improvement: Food and Drug Administration Activities and Engagement with the Voluntary Improvement Program” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Francisco Vicenty, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1534, Silver Spring, MD 20993–0002, 301–796–5577.

SUPPLEMENTARY INFORMATION:

I. Background

As part of the Center for Devices and Radiological Health’s (CDRH’s) 2016–2017 strategic priority to “Promote a Culture of Quality and Organizational Excellence,” CDRH envisions a future where the medical device ecosystem is