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

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–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

inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety. Among its other regulatory activities, FDA evaluates manufacturers' compliance with regulations governing the design and production of devices. Compliance with the ''Quality System Regulation,'' 21 CFR part 820, is a baseline requirement for medical device manufacturing firms.[1]

In an effort to elevate and enhance manufacturing practices and behaviors through which quality and safety of medical devices can be improved, FDA has collaborated with various stakeholders, brought together through the MDIC public-private partnership, to develop the CfQ Pilot Program. FDA announced the voluntary CfQ Pilot Program in the **Federal Register** on December 28, 2017 (82 FR 61575).

As in the CfQ Pilot Program, the VIP oversees third-party appraisers who evaluate voluntary industry participants, and the VIP assesses the capability and performance of key business processes using a series of integrated best practices. Those practices are detailed in the Information Systems Audit and Control Association Capability Maturity Model Integration (CMMI) system. CMMI provides a roadmap that guides improvement toward disciplined and consistent processes for achieving key business objectives, including quality and performance. The VIP uses a version of the CMMI appraisal appropriate for the medical device industry. This appraisal tool is referred to as the Medical Device Discovery Appraisal Program (MDDAP) model. The baseline appraisal using the MDDAP model covers 11 practices areas, such as Governance, Implementation Infrastructure, and Managing Performance and Measurement. Subsequent appraisals may include an alternate list of practice areas compared to the baseline set. As part of the VIP, and as in the CfQ Pilot Program, the program provides firms and FDA with information about the firm's capability and performance for activities covered in the third-party appraisal.

Details and results from the 2018 CfQ Pilot Program are outlined in MDIC's Case for Quality Pilot Report, available at *https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/voluntary-medical-device-manufacturing-and-product-quality-pilot-program.*

This voluntary program is currently only available to eligible manufacturers of medical devices regulated by CDRH and whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (including under sections 510(k), 513, 515, and 520) (21 U.S.C. 360(k), 360c, 360e, and 360j).

A notice of availability of the draft guidance appeared in the **Federal Register** of May 6, 2022 (87 FR 27165). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarifying what participants must demonstrate to benefit from the opportunities offered by VIP, explaining that program participation is not a substitute for an FDA inspection, and providing further detail regarding the role of FDA in VIP.

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 Fostering Medical Device Improvement: Food and Drug Administration Activities and Engagement with the Voluntary Improvement 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.* Persons unable to download an electronic copy of ''Fostering Medical Device Improvement: Food and Drug Administration Activities and Engagement with the Voluntary Improvement 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 GUI00020039 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 guidance also refers to previously approved FDA collections of information which are also subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; Guidance; or FDA form	Topic	OMB control No.
''Fostering Medical Device Improvement: Food and Drug Administration Activities and Engagement with the Voluntary Improvement Program''.	Voluntary Improvement Program (VIP)	0910–0922
807, subpart E	Premarket notification	0910–0120
7	Recalls	0910–0432
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
860, subpart D	De Novo classification process	0910–0844
803	Medical Device Reporting	0910–0437

[1] On February 23, 2022, FDA proposed to amend the device QS regulation, 21 CFR part 820, to align more closely with international consensus standards for devices (87 FR 10119; available at *https://www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments*). Specifically, FDA proposed to withdraw the majority of the current requirements in part 820 and instead incorporate by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices—Quality management systems for regulatory purposes, in part 820. As stated in that proposed rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the current part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. FDA intends to finalize this proposed rule expeditiously. When the final rule takes effect, FDA will also update the references to provisions in 21 CFR part 820 in this guidance to be consistent with that rule.

21 CFR part; Guidance; or FDA form	Topic	OMB control No.
806	Medical Devices; Reports of Corrections and Removals	0910–0359
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
807, subparts A through D	Medical Device Registration and Listing	0910–0625

Dated: September 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20016 Filed 9–14–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2654]

Informed Consent Forms for Studies that Enroll Client-Owned Companion Animals; Draft Guidance for Industry; 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 draft guidance for industry (GFI) #282 entitled ''Informed Consent Forms for Studies that Enroll Client-Owned Companion Animals.'' As used in this guidance, informed consent is a documented process by which an owner or owner's agent voluntarily confirms the owner's willingness to allow their animal(s) to participate in a particular study, after having been informed of all aspects of the study that may be relevant to the owner's decision to participate. A sponsor or investigator should ensure the owner is provided with adequate information and time to allow for an informed decision about voluntary participation in a clinical investigation. This draft guidance provides recommendations on informed consent forms (ICF) used for studies that enroll client-owned companion animals (dogs, cats, and horses). FDA's Center for Veterinary Medicine (CVM) recommends all studies conducted with client-owned companion animals use an ICF and be conducted in accordance with Good Clinical Practice (GCP) guidelines.

DATES: Submit either electronic or written comments on the draft guidance by November 14, 2023 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–2023–D–2654 for ''Informed Consent Forms for Studies that Enroll Client-Owned Companion Animals.'' 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.*

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

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See