

the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Steven Fleischer, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0809, [Steven.Fleischer@fda.hhs.gov](mailto:Steven.Fleischer@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft 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 This draft guidance provides recommendations on ICFs used for studies that enroll client-owned companion animals (dogs, cats, and horses). CVM recommends all studies conducted with client-owned companion animals use an ICF and be conducted in accordance with GCP guidelines.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Informed Consent Forms for Studies that Enroll Client-Owned Companion Animals.” 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 and section 571 of the Federal Food, Drug, and Cosmetic Act have been approved under OMB control number 0910-0032.

**III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 11, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2023-N-3721]

**Quality Management Maturity Program for Drug Manufacturing Establishments; Establishment of a Public Docket; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to solicit comments that will assist the Agency in developing a Quality Management Maturity (QMM) program for establishments manufacturing human drugs, including biological products, regulated by the Center for Drug Evaluation and Research (CDER).

**DATES:** Submit either electronic or written comments on the notice by December 14, 2023 to ensure that the Agency considers your comment.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments may not be considered. Electronic comments must be submitted on or before December 14, 2023. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 14, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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-N-3721 for “Quality Management Maturity Program for Drug Manufacturing Establishments; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**FOR FURTHER INFORMATION CONTACT:** Djamila Harouaka, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4160, Silver Spring, MD 20993-0002, 240-402-0224, [CDER-QMM@fda.hhs.gov](mailto:CDER-QMM@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Drug manufacturers can achieve higher levels of QMM by successfully integrating business and manufacturing operations with quality practices and technological advancements to optimize manufacturing process performance and product quality, enhance supply chain reliability, and foster proactive continual improvement. CDER is developing a voluntary program to promote QMM at drug manufacturing establishments. The goals of this program are: (1) to foster a strong quality culture mindset; (2) recognize establishments that have advanced quality management practices and acknowledge establishments that strive to continually improve those practices; (3) identify areas where quality management practices can be enhanced and provide suggestions for growth opportunities; and (4) minimize risks to

product availability to assure reliable market supply.

The QMM assessment is designed to appraise an establishment’s quality culture mindset, behaviors, and commitment to adopting best practices to effectively meet the needs of patients and consumers. QMM assessments would not be used to evaluate compliance with current good manufacturing practice (CGMP).

QMM assessments would be conducted by trained assessors, who would engage directly with establishments, either onsite or in a hybrid (onsite/remote) environment, for 2 to 5 business days. The QMM assessment will cover five practice areas: (1) management commitment to quality; (2) business continuity; (3) advanced pharmaceutical quality system; (4) technical excellence; and (5) employee engagement and empowerment. Within each practice area, the assessors would explore key elements to better understand an establishment’s QMM. Examples of elements covered under each practice area could include: management review and resource management (management commitment to quality practice area), supply planning and demand forecasting (business continuity practice area), data governance and process optimization (technical excellence practice area), effectiveness of the corrective action and preventive action process (advanced pharmaceutical quality system practice area), and rewards and recognition (employee engagement practice area). Each establishment’s responses, executed practices, and behaviors would be assessed using a standardized assessment protocol and an objective rubric, which is currently under development, to help identify areas of strength and potential areas with opportunities for improvement.

At a November 2, 2022, meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee, FDA sought to determine the support of academic and industry experts for CDER’s development of a QMM program. By a vote of 9-0, the committee affirmed that CDER should establish a QMM program to incentivize investments in mature quality management practices. During deliberations, committee members advised the Agency to continue to seek stakeholder input throughout the program’s development. Further information about the November 2022 Advisory Committee meeting, including event materials, is available on FDA’s website at <https://www.fda.gov/advisory-committees/advisory->

[committee-calendar/november-2-3-2022-pharmaceutical-science-and-clinical-pharmacology-advisory-committee-meeting](https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-2-3-2022-pharmaceutical-science-and-clinical-pharmacology-advisory-committee-meeting). For further information about QMM, relevant research, and previously conducted pilot programs, please see CDER’s QMM web page at <https://www.fda.gov/drugs/pharmaceutical-quality-resources/cder-quality-management-maturity>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

**II. Request for Comments**

FDA is opening a docket to solicit additional feedback from the public on CDER’s planned, voluntary QMM program. The public is invited to provide detailed comments on all aspects described in this notice. To facilitate this input, FDA has developed a list of questions. These questions are not exhaustive, and FDA welcomes other pertinent information the public would like to share on this topic. In all cases, FDA encourages the public to provide the reasoning and specific basis for any comments.

1. If you are a manufacturer, please identify the types of drug(s) produced in your establishment (e.g., active pharmaceutical ingredients, innovator drugs, innovator biologics, generics, biosimilars, or OTC monograph drugs). If you are not a manufacturer, please specify whether you are a purchaser, payor, pharmacy, healthcare provider, patient, regulator, supplier, distributor, contract service provider, or other (please describe).

2. What advantages do you anticipate that your sector (i.e., your organization and others like yours) would gain from CDER’s voluntary QMM program?

3. How would participation in a QMM program benefit you or your specific organization?

4. How would you use information from a QMM assessment if it were provided to your organization? For example, if your organization acts as a supplier or contract organization, would you consider sharing information from a QMM assessment with a potential client? If your organization enters into contracts with purchasers, would you consider sharing information from a QMM assessment with a purchaser? If your organization is a purchaser, would you consider requesting information from a QMM assessment?

5. What, if any, unintended consequences, roadblocks, or other concerns do you anticipate with a voluntary QMM program? What barriers to participation do you anticipate? Please explain. Which of these

unintended consequences might be unique to stakeholders like you? Why?

6. FDA anticipates that each establishment would be provided with a detailed report following their QMM assessment. What would you want such a report to contain?

7. With respect to the outcomes of a QMM assessment, what are your thoughts about making outcomes public? Would your thoughts be different if the outcomes were generally qualitative (e.g., descriptive information) versus quantitative (e.g., a numerical rating)?

8. What other feedback would you like the FDA to consider for a voluntary QMM program?

### III. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at <https://www.regulations.gov> as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Maguire, J., A. Fisher, D. Harouaka, N. Rakala, et al., 2023, "Lessons from CDER's Quality Management Maturity Pilot Programs," *The AAPS Journal*, 25(14), January 10, 2023, <https://doi.org/10.1208/s12248-022-00777-z>.
2. Fellows, M., T. Friedli, Y. Li, J. Maguire, et al., 2022, "Benchmarking the Quality Practices of Global Pharmaceutical Manufacturing to Advance Supply Chain Resilience," *The AAPS Journal*, 24(111), October 20, 2022, <https://doi.org/10.1208/s12248-022-00761-7>.

Dated: September 12, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-4060]

#### Medical Devices With Indications Associated With Weight Loss Guidances; Draft Guidances 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 two draft guidances entitled "Medical Devices with Indications Associated with Weight Loss—Clinical Study and Benefit-Risk Considerations" and "Medical Devices with Indications Associated with Weight Loss—Non-Clinical Recommendations." These draft guidance documents provide recommendations regarding clinical study design for devices with indications for use associated with weight loss, include discussion on how FDA considers the benefit-risk analysis to support such indications, and provide recommendations for the non-clinical testing to support premarket submissions for these medical devices. These draft guidances are not final nor are they for implementation at this time.

**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-2019-N-4060 for "Medical Devices with Indications Associated with Weight Loss—Clinical Study and Benefit-Risk Considerations" and "Medical Devices with Indications Associated with Weight Loss—Non-Clinical Recommendations." 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