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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--Premarket Considerations; 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 "Medical Devices with Indications Associated with Weight Loss--Premarket Considerations." This guidance document provides recommendations regarding non-clinical testing and clinical study design for medical devices with indications for use associated with weight loss to support premarket submissions. The guidance also includes discussion on how FDA considers the benefit-risk analysis to support such indications.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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-2019-N-4060 for "Medical Devices with Indications Associated with Weight Loss--Premarket Considerations." 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 "Medical Devices with Indications Associated with Weight Loss--Premarket Considerations" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301-796-6353.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides recommendations regarding non-clinical testing and clinical study design for medical devices with indications for use associated with weight loss to support premarket submissions. The guidance also includes discussion on how FDA considers the benefit-risk analysis to support such indications. Examples of indications associated with weight loss include indications for weight loss, weight reduction, weight management, or obesity treatment in patients who are overweight or have obesity. The recommendations reflect current review practices of premarket submissions for these devices and are intended to promote consistency and facilitate efficient review of these submissions.

Prior to issuing this guidance, FDA requested public comment on a concept for balancing the benefit of weight loss with the risks of adverse events in a discussion paper (September 2019, Docket No. FDA-2019-N-4060). FDA considered public comments and incorporated the feedback as appropriate in developing the draft guidance, "Medical Devices with Indications Associated with Weight Loss--Clinical Study and Benefit-Risk Considerations."

A notice of availability of the draft guidances "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" appeared in the *Federal Register* of September 15, 2023 (88 FR 63589). FDA combined the two draft guidances into one final guidance document for ease of use, since the scope of the draft guidances included the same device area. FDA also considered comments received and revised the language as appropriate in response to the comments. Edits to the final guidance include clarification on the use of sham controls, discussion of statistical analysis using modified intent-to-treat populations, inclusion of patient-reported outcomes as a factor to be considered as part of the benefit-risk evaluation, provision of additional reference citations, and addition of references

to FDA's Q-Submission Program, which can be used to request feedback on aspects of a proposed clinical study design.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on "Medical Devices with Indications Associated with Weight Loss--Premarket Considerations". 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.

FDA considered the applicability of Executive Order 14192, per Office of Management and Budget (OMB) guidance in M-25-20, and finds this action to be neither an EO 14192 regulatory nor an EO 14192 deregulatory action.

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 and at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Persons unable to download an electronic copy of "Medical Devices with Indications Associated with Weight Loss--Premarket Considerations" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00019046 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 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 and Early Payor Feedback Request Programs for Medical Devices	0910-0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910-0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073
50, 56	Protection of Human Subjects and Institutional Review Boards	0910-0130
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies	0910-0119

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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