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.

[FR Doc. 2023–20015 Filed 9–14–23; 8:45 am]

BILLING CODE 4164–01–P

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 These draft guidance documents provide recommendations regarding clinical study design for devices with indications for use associated with weight loss, include discussion on how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

''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 draft guidance document entitled ''Medical Devices with Indications Associated with Weight Loss—Clinical Study and Benefit-Risk Considerations'' or ''Medical Devices with Indications Associated with Weight Loss—Non-Clinical Recommendations'' 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: April Marrone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2604, Silver Spring, MD 20993–0002, 240–402–6510.

SUPPLEMENTARY INFORMATION:

I. Background

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 non-clinical testing to support premarket submissions for these medical devices. These devices may be indicated for weight loss, weight reduction, weight management, or obesity treatment in patients who are overweight or have obesity. The recommendations and considerations reflect current review practices and are intended to promote consistency and facilitate efficient review of these submissions.

Prior to drafting these guidances, 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.''

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidance documents, when finalized, will represent the current thinking of FDA on ''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.'' They do not establish any rights for any person and are 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 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/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* or *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—Clinical Study and Benefit-Risk Considerations (document number GUI00021016)'' or ''Medical Devices with Indications Associated with Weight Loss—Non-Clinical Recommendations (document number GUI00019046)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 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 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: Informed Consent; Institutional Review Boards.	0910–0130
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: September 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20029 Filed 9–14–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Change in Federal Award Closeout Provisions

AGENCY: Office of the Assistant Secretary for Financial Resources (ASFR), Department of Health and Human Services (HHS or the Department).

ACTION: Notice.

SUMMARY: HHS will follow the Federal award Office of Management and Budget (OMB) closeout provisions modified the closeout provisions rather than the HHS-specific closeout provisions.

FOR FURTHER INFORMATION CONTACT: Johanna Nestor at *Johanna.Nestor@hhs.gov* or (202) 631–0420.

SUPPLEMENTARY INFORMATION:

Background: In 2014, HHS codified the Uniform Administrative Requirements, Cost Principles, and Audit Requirements (UAR) for HHS Awards at 45 CFR part 75. 79 FR 75889 (Dec. 19, 2014). This codification included HHS-specific language, including the adoption of the closeout provisions at 45 CFR 75.381. In 2020, the Office of Management and Budget modified the closeout provisions for Federal awards at 2 CFR 200.344. 85 FR 49506 (Aug. 13, 2020). These modifications:

- Increase the number of days for recipients to submit closeout reports and liquidate all financial obligations from 90 calendar days to 120 calendar days after the end of the period of performance.
- Require awarding agencies to complete closeout actions no later than one year after the end of the period of performance unless otherwise directed by authorizing statutes.
- Require awarding agencies to close out awards within one year of the end of the period of performance based on available information and report the recipient to the OMB-designated integrity and performance system (currently Federal Awardee Performance and Integrity Information System (FAPIIS)).

The HHS-specific closeout provisions at 45 CFR 75.381 are more restrictive than 2 CFR 200.344 as modified. This may lead to recipient confusion and inconsistencies in closeout timing government-wide. Additionally, the different provisions may result in report submission delays, which can affect closeout task reconciliation and effective completion. Adhering to the 2 CFR 200.344 closeout provisions would provide more time for recipient compliance and conform with other Federal awarding agencies, thus promoting greater equity and fairness.

Action: For the reasons stated above, effective October 1, 2023, HHS will follow the 2 CFR 200.344 closeout provisions This action will minimize the burden on the internal and external grants communities while ensuring the timely closeout of HHS awards.

William D. Bell IV,

Deputy Assistant Secretary for Grants.

[FR Doc. 2023–19954 Filed 9–14–23; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Substance Use and Mental Health Services Survey (N–SUMHSS) (OMB No. 0930–0386)—Revision

Under section 505 of the Public Health Service Act (42 U.S.C. 290aa–4), SAMHSA is required to conduct annual collection of data on substance use and mental health. Selected information collected from the N–SUMHSS is also published on SAMHSA's *FindTreatment.gov* for persons seeking treatment for mental and substance use disorders in the United States. *FindTreatment.gov* is authorized by the 21st Century Cures Act (Pub. L. 114–255, section 9006; 42 U.S.C. 290bb–36d).

In 2021, SAMHSA combined the National Survey of Substance Abuse Treatment Services (N–SSATS) and the National Mental Health Services Survey (N–MHSS) into the N–SUMHSS to reduce the burden on facilities offering both substance use and mental health services, optimize government resources to collect data, and enhance the quality of data collected on the treatment facilities.

The N–SUMHSS is the most comprehensive national source of data on substance use and mental health treatment facilities. On an annual basis, the N–SUMHSS collects information on the facility location, characteristics, and utilization of substance use and mental health treatment services. The survey also collects client counts on individuals receiving services at these facilities. There is an increasing need to collect and maintain data on current and accurate numbers of clients in treatment at the local level for communities to assess capacity and estimate resource requirements. This information on substance use and mental health services has assisted with communities to better respond to life changing events, (*i.e.,* hurricane) and plan for service demands in the event of a natural disaster (*i.e.,* earthquakes).

SAMHSA also maintains the Inventory of Substance Use and Mental Health Treatment Facilities (I–TF) (previously known as the Inventory of Behavioral Health Services [I–BHS]). The I–TF is a master list of all known substance use and mental health treatment facilities in the United States. It also serves as the universe population for the N–SUMHSS.

SAMHSA is requesting OMB approval of revisions to the N–SUMHSS and I–TF related data collections, to include changes to the following instruments:

N–SUMHSS Questionnaire

- *Q1a:* added to clarify if facilities reported providing mental health treatment services in Q1 also provide substance use treatment services, to help respondents understand how to respond accurately and ensure appropriate survey module(s) are completed.