between testing in community-based and clinical-based settings and linkage to HIV care, ART initiation, and viral suppression.

Data will be used to compare an HIV RNA POC NAT to standard lab-based HIV testing. The data will be analyzed and disseminated to describe the real-world performance and clinical usefulness of HIV RNA POC NAT technology. Data will be gathered through: clinical site extraction of electronic medical records for use as a retrospective baseline comparator after study implementation; a longitudinal, prospective study of persons without HIV seeking HIV testing or PrEP services; a longitudinal, prospective study of persons with HIV seeking STI testing; a randomized clinical trial of HIV POC NAT or standard of care for persons with HIV; a survey, interviews, and focus groups to understand HIV POC NAT acceptability among persons without HIV and persons with HIV; an assessment of the performance of an HIV POC NAT among persons with HIV; and an acceptability/feasibility assessment among clinical and community providers and costing analyses.

CDC is requesting OMB approval for estimated 880 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Participating Clinic	Baseline data collection variables list.	2	1	2	4
	Monthly study report form	2	12	15/60	6
Participants in prospective study of persons without HIV seeking HIV testing and/or PrEP services.	Release of information form	850	1	10/60	142
	Study visit survey	850	1	15/60	213
Participants in prospective study of persons with HIV seeking STI testing.	Release of information form	50	1	10/60	8
	Study visit survey	50	1	15/60	13
Participants in RCT of POC NAT or Standard of Care for persons with HIV.	Release of information form	212	1	10/60	35
	Study visit survey	212	1	15/60	53
Participants in survey group examining POC NAT acceptability.	POC NAT acceptability survey	500	1	20/60	167
Participants in cross-sectional comparison of several point-of-care NATs.	Release of information form	333	1	10/60	56
	Study visit survey	333	1	15/60	83
Participants in the acceptability/feasibility assessment.	POC NAT acceptability survey, focus group, or interview.	100	1	1	100
Total					880

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2025–00166 Filed 1–7–25; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0435]

Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction; 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 entitled ''Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction.'' This draft guidance provides recommendations to industry regarding the development of drugs and biological products regulated within the Center for Drug Evaluation and Research intended for reduction and long-term maintenance of body weight in patients with obesity or overweight. This draft guidance revises and replaces the draft guidance for industry ''Developing Products for Weight Management'' issued in February 2007.

DATES: Submit either electronic or written comments on the draft guidance by April 8, 2025 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–2007–D–0435 for ''Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction.'' 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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: John Sharretts, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–4678.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction.'' This draft guidance is intended to provide recommendations to industry regarding the development of drugs and biological products regulated within the Center for Drug Evaluation and Research in FDA intended for reduction and long-term maintenance of body weight in patients with either obesity or who are classified as overweight based on body mass index and also have weight-related medical problems. This draft guidance revises and replaces the draft guidance for industry ''Developing Products for Weight Management'' issued on February 15, 2007 (72 FR 7441), which no longer reflects our current state of knowledge and the state of medical product development.

This draft guidance focuses on the design of trials to demonstrate sustained medical weight loss in individuals with obesity and those with body mass index classified as overweight who also have weight-related comorbidities. Medical weight loss is defined within the draft guidance as a long-term reduction in excess body fat with a goal of reduced morbidity and mortality. The weight reduction indication comprises the concepts of both initial weight loss and weight maintenance (*i.e.,* prevention of weight regain) for a minimum of 1 year.

Major topics in this draft guidance include discussion of appropriate adult and pediatric participants to enroll in clinical trials for chronic weight management, principles of phase 1 and phase 2 trials, and detailed discussion of phase 3 trials, including trial design, size, and duration; efficacy endpoints; safety evaluation; and statistical principles. Special topics include trial considerations for patients with diabetes mellitus, assessment of weight management products in combination, and trial considerations for assessment of pediatric patients.

This 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 ''Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction.'' 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). This guidance refers to collections of information from ''individuals under treatment or clinical examination in connection with research,'' which are not subject to review by OMB under 5 CFR 1320.3(h)(5). The collections of information in 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for new drug applications, including formal meetings between FDA and sponsors or applicants have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 58, Good Laboratory Practice for Nonclinical Studies, has been approved under OMB control number 0910–0119.

III. Electronic Access

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

Dated: December 30, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00237 Filed 1–7–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–3780]

Developing Drugs for Optical Imaging; 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 entitled ''Developing Drugs for Optical Imaging.'' The purpose of this guidance is to provide recommendations to sponsors regarding clinical trial design features that support development and approval of optical imaging drugs that are used in conjunction with imaging devices and intended as intraoperative aids for the detection of pathology such as tumors or to enhance the conspicuity of normal anatomical structures.

DATES: Submit either electronic or written comments on the draft guidance by April 8, 2025 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–2024–D–3780 for ''Developing Drugs for Optical Imaging.'' 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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Libero Marzella, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2050; or Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353.

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Developing Drugs for Optical Imaging.'' The purpose of this guidance is to provide recommendations to sponsors regarding clinical trial design features that support development and approval of optical imaging drugs that are used in conjunction with imaging devices and intended as intraoperative aids for detection of pathology such as tumors or to enhance the conspicuity of normal anatomical structures.