received from the public. The final determinations with respect to reconsidered codes are not subject to further reconsideration. With respect to the final determinations for new test codes, the public may request reconsideration of the basis and amount of payment as set forth in § 414.509.

III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the CLFS Annual Public Meeting registration. Beginning May 1, 2026 and ending May 29, 2026, registration may be completed by presenters and in-person attendees. Individuals who intend to view and/or listen to the meeting virtually do not need to register. Presenter registration and individuals who intend to attend the meeting at the CMS campus must register online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/*. On this web page, under the heading ''Meeting Notice, Registration, Agenda, & Other Important Materials'' you will find a link entitled ''Register for CLFS Annual Meeting.'' Click this link and enter the required information. All of the following information must be submitted when registering:

- Name.
- Organization/Company name.
- Email addresses.
- Indicate if individual is a presenter.
- Indicate how individual is participating in the meeting (that is, in-person or virtual).
- Indicate if individual is a ''Foreign National'' visitor. Note: An additional review process is required for all foreign national visitors.

When registering, individuals who want to make a presentation must also specify the test codes on which they will be presenting comments. Confirmation will be sent upon receipt of the registration. Individuals must register by the date specified in the **DATES** section of this notice.

Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by the date specified in the **DATES** section of this notice. Additionally, registration information must reflect individual-level content and not reflect the name of an organization. For example, an organization cannot request to register a group of individuals without specifying registration details for each individual being registered. See section V. of this notice for further information.

After registering, a confirmation email will be sent upon receipt of the registration. The email will provide information to the presenter or in-person attendee in preparation for the meeting. Registration is only required for individuals giving a presentation during the meeting or attending the meeting at the CMS campus. Presenters or in-person attendees must register by the deadline specified in the **DATES** section of this notice.

If you are not presenting during the CLFS Annual Public Meeting or cannot attend in person, you may view the meeting via webinar or listen-only by teleconference. If you would like to listen to or view the meeting, teleconference dial-in and webinar information will appear on the final CLFS Annual Public Meeting agenda, which will be posted on the CMS website when available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/*.

IV. Special Accommodations

Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the resource box (*CDLT_Annual_Public_Meeting@cms.hhs.gov*). The deadline for submitting this request is listed in the **DATES** section of this notice.

V. Security, Building, and Parking Guidelines

This hybrid meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. We suggest that you arrive at the CMS campus and parking facilities between 9:00 a.m. and 9:45 a.m. E.D.T., so that you will be able to arrive promptly at the meeting by 10:00 a.m. E.D.T. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. We note that the public may not enter the CMS building earlier than 9:15 a.m. E.D.T. (45 minutes before the convening of the meeting).

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–08511 Filed 4–30–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3499]

Obesity and Drug Dosing: Clinical Pharmacology Considerations; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket entitled ''Obesity and Drug Dosing: Clinical Pharmacology Considerations.'' The Agency is soliciting input from interested persons on assessing the effect of obesity on drug pharmacokinetics and

pharmacodynamics during drug (including biological product) development. These assessments could potentially inform whether obesity impacts the safety and effectiveness of the drug and dosing recommendations for obese patients.

DATES: Submit either electronic or written comments by June 30, 2026.

ADDRESSES: FDA is establishing a docket for public comment on this notice. The docket number is FDA–2026–N–3499. The docket will close on June 30, 2026. Submit either electronic or written comments by June 30, 2026. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 30, 2026. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 30, 2026. 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.

You may submit comments 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–2026–N–3499 for ''Obesity and Drug Dosing: Clinical Pharmacology Considerations; Request for Comments.'' 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.

FOR FURTHER INFORMATION CONTACT: Martina Sahre, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9659.

SUPPLEMENTARY INFORMATION:

I. Background

Obesity is a critical and increasingly prevalent public health concern in the United States affecting approximately 20% of children [1] and approximately 40% of adults.[2] It is linked to a variety of comorbidities such as diabetes and heart disease. The U.S. Centers for Disease Control and Prevention (CDC) defines obesity as having a body mass index of ≥30 kg/m^2 for adults and a body mass index at or above the 95th percentile (based on age and sex) for children.[1,2] Despite its high prevalence, the effect of obesity on drug pharmacokinetics, pharmacodynamics, effectiveness, and safety is not consistently assessed in clinical trials, except in certain therapeutic areas (*e.g.,* obesity, Type 2 diabetes mellitus, sleep apnea). Furthermore, obesity-related information on these aspects is often absent in drug product labels.

Obesity is reported to affect the pharmacokinetics and pharmacodynamics of drugs in several ways: (1) lipophilic drugs can show increased distribution into fat tissues; (2) absorption can be altered due to changes in gastric transit times and gastrointestinal pH values; (3) metabolism and excretion could be altered due to an impact on drug-metabolizing enzymes, transporters, or changes in renal clearance; and (4) the sensitivity of drug targets could be altered. The impact of body size (usually total body weight) is typically considered as part of population pharmacokinetic analysis. If identified as a significant covariate in population pharmacokinetic analysis, the need for dosing based on body weight, body mass index, or body surface area is routinely assessed. However, limited enrollment of obese patients in clinical trials—particularly patients with morbid obesity—limits pharmacokinetic and pharmacodynamic assessments across a full range of body sizes.

[1] U.S. Centers for Disease Control and Prevention (CDC), 2024, Childhood Obesity Facts, CDC, accessed May 8, 2025, *https://www.cdc.gov/obesity/childhood-obesity-facts/childhood-obesity-facts.html.*

[2] CDC, 2024, Adult Obesity Facts, CDC, accessed May 8, 2025, *https://www.cdc.gov/obesity/adult-obesity-facts/index.html.*

II. Request for Information and Comments

FDA invites interested persons to provide detailed information and comments on relevant considerations for evaluating the impact of obesity on drug pharmacokinetics and pharmacodynamics and the need for specific dosage recommendations. Please provide the rationale for your suggestions and include supporting data if available.

FDA is particularly interested in responses to the following overarching questions:

1. Body mass index is often used to identify and classify the degree of obesity. Is the categorization of body mass index sufficient for evaluating the impact of obesity on drug pharmacokinetics or pharmacodynamics and to inform recommendations for use in the obese population? If not, what other pragmatic measures (*e.g.,* anthropometric, biochemical, clinical) can be used in drug development to assess the impact of obesity on drug pharmacokinetics or pharmacodynamics and develop appropriate dosing recommendations for adults and pediatric patients? Please also discuss the applicability of body mass index or other measures in pediatric patients with obesity.

2. What drug-specific characteristics or therapeutic-area/disease-related considerations are important when assessing the impact of obesity on pharmacokinetics or pharmacodynamics?

3. How should the impact of obesity on pharmacokinetics or pharmacodynamics, and potentially safety and effectiveness, be assessed throughout drug development (*e.g.,* standalone phase 1 studies, using model-informed drug development approaches to evaluate data from late phase trials that can also incorporate available data from other phases of drug development)? Please also comment on any specific study design considerations for the different approaches proposed and the timing of such assessments.

III. Electronic Access

Persons with access to the internet may obtain relevant clinical pharmacology guidances at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Citation Authority: 21 CFR 312, 21 CFR 314, and 21 CFR 601.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–08521 Filed 4–30–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3947]

Impacts of Patient-Focused Drug Development Meetings; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is establishing a public docket to collect examples about how previous patient-focused drug development (PFDD) meetings have impacted stakeholders' drug development efforts. This includes impacts on community engagement, research priorities, advocacy strategies, medical product development programs, clinical practice, and other areas of interest.

DATES: Either electronic or written comments on the notice must be submitted by June 30, 2026

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 30, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2026–N–3947 for ''Impacts of Patient-Focused Drug Development Meetings; Establishment of a Public Docket; Request for Information and 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