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

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: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–8112, *Ethan.Gabbour@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As directed by Section 569C of the Federal Food, Drug, and Cosmetic Act, as amended by Section 3001 of the 21st Century Cures Act (Pub. L. 114–255), FDA has developed and implemented strategies to obtain patient input to inform drug development and regulatory decision-making. FDA-led PFDD and externally led-PFDD (EL–PFDD) meetings provide a structured opportunity to hear directly from patients, caregivers, family members, and patient advocates. These meetings center on the aspects of a disease or condition and its treatment that are most meaningful to patients, including symptoms, effects on daily life, and experiences with available therapies.

Patient input from these meetings can inform medical product development, research priorities, and regulatory oversight. In response to stakeholder requests to better understand the outcomes of these meetings, FDA is seeking to collect information about their subsequent impacts. The Agency recognizes that many significant outcomes such as interactions within patient communities, between patient groups and medical product developers, or among clinicians occur in forums to which FDA is not typically a party. Similarly, changes made by medical product developers in response to patient input may not be communicated to FDA outside of a formal regulatory submission.

II. Issues for Consideration and Request for Information

FDA is issuing this request for information to gain a better understanding of how patient input from FDA-led PFDD and EL–PFDD meetings has informed stakeholder activities including research, product development, and patient care, outside of specific regulatory decisions. FDA invites input from all interested parties, including patient organizations, medical product developers, healthcare providers, and academic researchers.

FDA is seeking information that addresses the following:

1. How have PFDD meetings informed patient communities and stakeholder engagement activities?
2. What scientific questions, research initiatives, or identified gaps in the understanding of a disease or condition have resulted from PFDD meetings?
3. In what ways has patient input from PFDD meetings informed medical product development programs or strategies (*e.g.,* endpoint development, clinical trial design, identification of unmet needs, industry partnerships)?
4. How has patient input gathered during PFDD meetings been integrated into or otherwise affected clinical practice?
5. Please describe any other outcomes or effects resulting from PFDD meetings, with examples, that were not addressed in the questions above.

FDA encourages respondents to provide specific examples in their answers where possible.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–08524 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–4268]

Medical Devices; Exemptions From Premarket Notification: Certain Class II Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to exempt from premarket notification requirements certain class II clinical toxicology test system devices. FDA is publishing this notice and requesting public comment in accordance with procedures established by the 21st Century Cures Act. This notice does not represent FDA's final determination with respect to the devices included in this document. FDA will review any comments submitted within the 60-day comment period and will further consider whether the exemption described in this notice should be modified prior to publication of its final determination in the **Federal Register**.

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

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- *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

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- 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.''