



4511 North Himes Ave., Suite 250
Tampa, FL 33614

(800) 717-3117
(813) 872-7835
Fax: (813) 873-7838

info@obesityaction.org
www.obesityaction.org

June 26, 2026

Acting Commissioner Kyle Diamantas
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. FDA–2026–N–3499 – Obesity and Drug Dosing: Clinical Pharmacology Considerations;
Request for Comments**

Dear Acting Commissioner Kyle Diamantas,

The Obesity Action Coalition (OAC) appreciates the opportunity to provide comments on the FDA’s request for input regarding the impact of obesity on drug dosing. We commend the Agency for prioritizing this important issue and for recognizing the need to better understand how medications work for people affected by the disease of obesity.

Obesity is a complex, chronic disease influenced by a range of biological, genetic, environmental and behavioral factors. It can significantly affect how the body absorbs, distributes, metabolizes and eliminates medications. Despite this, many drugs are approved without sufficient data on how they perform in people affected by obesity. This gap creates uncertainty for patients and healthcare providers and may impact both the safety and effectiveness of treatment.

At the FDA’s obesity-focused workshop in November 2022, Agency leadership acknowledged significant gaps in available data regarding the pharmacokinetics of medications in patients with obesity and raised concerns about whether this population is consistently receiving safe and effective treatment. This acknowledgment underscores an important patient safety issue affecting a substantial portion of the U.S. population.

More than 40% of U.S. adults, representing over 100 million people, are affected by obesity, yet this population is often underrepresented in clinical research. Evidence shows that many medications are not routinely tested in people affected by obesity prior to approval, and labeling frequently lacks guidance specific to this population. In some cases, differences in how medications behave in the body are only identified after approval, leaving clinicians without clear direction for appropriate dosing.

We agree with the direction of the agency and remain concerned that when obesity-specific pharmacokinetic data becomes available through peer-reviewed research, it does not consistently result in timely updates to FDA-approved labeling or clear clinical guidance. This disconnect raises serious concerns about whether current regulatory processes are adequately supporting patient safety and equipping clinicians with the information

needed to deliver appropriate care. We applaud the FDA for taking meaningful steps to ensure that drug development and evaluation more consistently reflect the needs of people affected by obesity and offer a few points for consideration.

First, we urge the FDA to recognize obesity as a critical factor in drug development and regulatory review. Current measures, such as body mass index (BMI), may not fully capture the complexity of how obesity influences drug response. We encourage the Agency to consider additional clinical and biological factors, including body composition and metabolic differences, when evaluating dosing and safety.

Second, we strongly recommend increasing the inclusion of people affected by obesity in clinical trials across therapeutic areas. Given the prevalence of obesity in the United States, it is essential that study populations reflect real-world patients. Without adequate representation, prescribing information may lack clear, evidence-based guidance for this population.

Third, we call for clearer expectations for when and how drug developers should assess dosing differences in people affected by obesity. This includes consideration of dedicated studies, modeling approaches and post-market data collection to ensure that medications are used safely and effectively across various patient populations.

Fourth, we encourage the FDA to require that clinically meaningful findings related to obesity and drug response be transparently reflected in product labeling. Patients and healthcare providers need clear, actionable information to make informed treatment decisions.

Fifth, we encourage FDA to utilize “people-first” language in all its communications regarding individuals affected by obesity. Bias and stigma can be shown in many ways, but one of the most popular ways it is shown is through the absence of people-first language. Labeling individuals as “obese” creates negative feelings toward individuals with obesity and perpetuates weight bias.

Finally, improving the evidence base for medication use in people affected by obesity is essential to advancing access to care. When dosing guidance is unclear or incomplete, it can create barriers to appropriate treatment and limit the ability of patients to benefit from safe and effective therapies. Ensuring that medications are studied and labeled with this population in mind will support better health outcomes and more informed clinical decision-making.

The OAC and our community of more than 100,000 members remain committed to working alongside the FDA and other stakeholders to improve the quality, safety and accessibility of care for people affected by obesity. Thank you again for your leadership in addressing this critical issue and for the opportunity to provide input. Please contact Dr. Tracy Zvenyach, PhD at tzvenyach@obesityaction.org with any questions.

Sincerely,



Joe Nadglowski
President & CEO
Obesity Action Coalition