



FDA Unveils Draft Guidance on Developing Drugs and Biological Products for Weight Reduction

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On January 7, the FDA made available draft guidance on the development of drugs and biological products for weight reduction within the Center for Drug Evaluation and Research intended for reduction and long-term maintenance of body weight in patients with obesity or who are overweight. Notably, this draft guidance includes recommendations with respect to the clinical assessment of weight reduction drugs in both adults and pediatric patients, revising and replacing the draft guidance for industry “Developing Products for Weight Management” issued in February 2007. Obesity presents significant implications for patients, public health and our nation’s health care system as annual obesity-related medical care costs in the United States are estimated to be nearly \$173 billion. The issuance of this draft guidance comes against the backdrop of ongoing policy considerations related to the coverage of anti-obesity medications and how best to tackle chronic disease. The FDA has requested comments be submitted by April 8, 2025.

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