NATIONAL ASSOCIATION OF Manufacturers

June 26, 2026

Dr. Michael Davis, MD, Ph.D.
Acting Director
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2018-N-3240: *List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act*

Dear Dr. Davis,

The National Association of Manufacturers (NAM) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) in response to its proposal not to include semaglutide, tirzepatide, and liraglutide on the statutory list of bulk drug substances eligible for compounding under 503B—also known as the 503B Bulks List. The NAM strongly supports FDA's proposal and urges the agency to finalize it without delay.

The NAM is the largest manufacturing association in the United States, representing manufacturers of every size, in every industrial sector, and in all 50 states. Manufacturing employs nearly 13 million men and women, contributes $2.94 trillion annually to the U.S. economy and accounts for nearly 53% of all private-sector research and development.

Manufacturers have a deep commitment to providing health benefits to their workers and want to be sure that manufacturing employees and their families have access to the FDA-approved medications they need. Health benefits are an integral part of manufacturing DNA—even with the consistent challenge of rising healthcare costs,[1] 95% of manufacturing employees are eligible for health insurance benefits, and 80% of those participate in a workplace healthcare plan.[2]

A growing problem in the American healthcare system is the rapid expansion of compounded medications—including compounded GLP-1s—that do not meet FDA's rigorous standards for safety and efficacy, are not FDA-approved, and for which there is no demonstrated clinical need. Not only are mass compounders circumventing patents and intellectual property rights, they are also exposing millions of Americans to substandard drugs that put their health at risk. Mass production and distribution of compounded drugs without rigorous FDA oversight has given patients access to medications that may harm them more than help them.[3]

FDA's 503B Bulks List identifies bulk drug substances—active pharmaceutical ingredients (APIs)—for which there is a clinical need for outsourcing facilities to compound under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Inclusion on this list permits outsourcing facilities to compound drug products using these substances without submitting a full new drug application.

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[1] National Association of Manufacturers, Q1 2026 Manufacturers' Outlook Survey (March 12, 2026). Available at https://nam.org/wp-content/uploads/securepdfs/2026/03/NAM_Q1_2026_Outlook_Write_Up.pdf

[2] Kaiser Family Foundation, *2025 Employer Health Benefits Survey* (Oct. 22, 2025). Available at https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2025-Annual-Survey.pdf

[3] U.S. Food and Drug Administration, FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss (February 2, 2026). Available at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss

Given the serious risks associated with compounded GLP-1s, manufacturers strongly support FDA's proposal to deny the nominations of semaglutide, tirzepatide, and liraglutide for inclusion on the 503B Bulks List.

Patient Safety Concerns

Compounded GLP-1s may be unsafe due to unsterile manufacturing conditions, may have incorrect potency or dosing, may be contaminated or contain impurities, may contain APIs from unregulated and uninspected foreign facilities, and may contain APIs that are research- or animal-grade instead of human-grade. Each of these violations puts patients at risk. As an example, FDA has received thousands of reports of adverse events associated with compounded GLP-1 drugs, with patient symptoms ranging from vomiting, sepsis, anaphylaxis, and liver failure to hospitalization and death. Since 2022, over 75,000 vials and syringes of compounded GLP-1s have been recalled due to safety concerns.

Worker safety is manufacturers' top priority, which is why the steep increase in adverse events from mass-compounded drugs is particularly concerning. When an FDA-approved drug is available and medically appropriate for a patient, the unnecessary risks posed by compounded alternatives are simply too significant to justify their use. Because of FDA's limited oversight and enforcement mechanisms over the behaviors of 503B compounding facilities, the agency has been unable to adequately tamp down on unsafe compounded drugs to protect patients. However, manufacturers appreciate the efforts FDA has taken to reprimand these bad actors, including issuing warning letters to non-compliant outsourcing facilities, pursuing injunctions against unlawful compounders, and placing facilities on import alert for repeated violations.

FDA Regulatory Process

FDA's regulatory framework for prescription drugs is the gold standard around the world—and for good reason. Compounding should be an exception to this framework for limited situations as determined by a singular patient's particular medical needs or if the substance falls on FDA's drug shortage list. Compounding should not be an additional avenue to make mass compounded drugs outside of FDA's oversight, inspection, and approval processes. 503B compounding facilities must register with FDA but are not necessarily inspected by FDA before they begin producing drugs. In fact, many 503B facilities have never been inspected by the agency. If FDA were to include semaglutide, tirzepatide, and liraglutide on the 503B Bulks List, it would set a dangerous precedent and legitimize the unregulated mass-compounding of other prescription drugs where patients have FDA-approved options.

Further, compounders have engaged in deceptive advertising—marketing their mass-compounded GLP-1s to imply equivalence to FDA-approved drugs made in FDA-inspected facilities. Consumers are misled to believe the compounded drugs they are taking have met the same safety and efficacy standards as FDA-approved drugs, when this is not the case and these drugs are more likely to be unsafe.

Impact On Manufacturing Investments

Manufacturers have invested substantial resources in researching, developing, and bringing to market the FDA-approved GLP-1s that are transforming patient care. These investments reflect years—often more than a decade—of rigorous clinical trials, regulatory submissions, and manufacturing scale-up, all conducted under FDA's robust oversight. The development of semaglutide, tirzepatide, and liraglutide alone has required billions of dollars in research and development investments, supporting tens of thousands of high-paying American jobs in manufacturing, research and development, quality assurance, and supply chain operations.

Expanding the 503B Bulks List to include these substances would directly undermine those investments. Manufacturers have made these investments in reliance on a regulatory system that rewards quality and innovation—the incentives that Congress designed to ensure a robust pipeline of safe and effective therapies for American patients. Allowing compounders to free-ride on the innovators' investment—without bearing the cost of clinical trials, without meeting FDA manufacturing standards, and without respecting intellectual property rights—sends a concerning signal to the manufacturers that drive pharmaceutical innovation for American patients.

The consequences extend well beyond GLP-1s. If FDA signals that compounders are permitted to mass-replicate innovator drugs without regard for the regulatory process, manufacturers will face reduced incentives to invest in the next generation of breakthrough therapies. The result could be fewer new treatments, fewer manufacturing jobs, and a weakened American pharmaceutical industry—outcomes that would harm patients and the broader economy alike.

Lack of Clinical Need

Manufacturers agree with FDA's determination that there is no clinical need for compounded GLP-1s. The personalization of compounded GLP-1s in which some facilities have engaged are not clinically necessary and introduce additional risks for patients. Should a patient truly need a dose adjustment, as determined by a provider, this can be achieved with sterile-to-sterile compounding using an FDA-approved finished dosage form. The agency correctly concluded in this proposal that there is no need to use untested bulk drug substances to create compounded GLP-1s.

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Manufacturers have significant patient safety and manufacturing investment concerns with bulk compounded medications, and we appreciate FDA's attention to this issue and consideration of these comments. The NAM urges FDA to expeditiously finalize the exclusion of semaglutide, tirzepatide, and liraglutide from the 503B Bulks List to protect patients, preserve the integrity of the FDA approval process, and safeguard the investments that drive American manufacturing, jobs, and innovation. Manufacturers look forward to continuing to work on our shared health care priorities to ensure that manufacturing workers, and all Americans, have access to safe and effective medications.

Sincerely,

Jake Kuhns
Vice President, Domestic Policy