July 17, 2026

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2018-N-3240-0377

Support for FDA's Proposed Determination Regarding Semaglutide, Tirzepatide, and Liraglutide

To Whom It May Concern:

The undersigned patient advocacy, consumer protection, public health, and chronic disease organizations write in support of the Food and Drug Administration's proposed determination that semaglutide, tirzepatide, and liraglutide should not be added to the 503B bulks list.

Our organizations represent millions of Americans living with obesity, diabetes, cardiovascular disease, and other chronic conditions. We strongly support patient access to safe, effective treatments and recognize that compounding serves an important role when a patient's medical needs cannot be met by an FDA-approved medicine. However, compounding should remain a carefully limited exception—not a routine substitute for approved therapies.

Patients deserve confidence that, wherever possible, the medicines they receive have been rigorously evaluated for safety, effectiveness, manufacturing quality, and consistency. FDA-approved medicines undergo extensive review before reaching patients. Compounded products do not.

FDA's proposed determination appropriately concluded that there is no demonstrated clinical need for outsourcing facilities to compound from these bulk drug substances. To date, we have not seen evidence establishing that FDA-approved versions of semaglutide, tirzepatide, or liraglutide are medically unsuitable for a substantial patient population or that routine compounding from bulk drug substances is necessary to address an unmet patient need. Patients today can already choose from a wide variety of FDA-approved doses and formats—including oral versions—giving doctors and patients real options without turning to untested compounded versions. And untested alternatives like adding vitamins and other substances are unproven and expose patients to real patient safety risks. Instead, these are a clear pretext to circumvent important public health safeguards for patients. There is no evidence that bulk-compounded versions of these products are needed to address a demonstrated gap in patient care.

The FDA approval system exists to protect patients. Preserving public confidence in that system requires maintaining clear distinctions between FDA-approved medicines and compounded alternatives. Allowing the bulks list to become a pathway for large-scale production of unapproved copies of commercially available medicines risks increasing patient confusion, undermining the protections from the FDA approval process, and sending a message to drug developers that the years of research and development needed to bring new treatments to patients may not be worth the investment.

As organizations dedicated to patient welfare, we are increasingly concerned by evidence that

many patients do not fully understand the differences between FDA-approved medicines and compounded alternatives. Patients often assume products containing the same active ingredient have undergone the same review and meet the same standards. In reality, compounded products do not undergo FDA premarket review for safety, effectiveness, or quality. Survey data paints a troubling picture: nearly nine out of ten consumers who bought GLP-1 products online believed FDA had reviewed those products for safety—when it had not.

This confusion matters because patients are making important health care decisions based on incomplete information. That problem is made worse by aggressive online marketing that blurs the line between FDA-approved medicines and compounded alternatives—prompting FDA itself to issue warnings to dozens of telehealth companies for misleading consumers. Patients deserve transparency about what they are receiving, how it was produced, what evidence supports its use, and what regulatory standards apply.

We are also concerned by reports of dosing errors, product quality concerns, adverse events, and other patient safety issues associated with compounded GLP-1 products. When researchers compared safety records, they found that compounded GLP-1 products were associated with more hospitalizations and more product quality problems than the FDA-approved versions. While no medical treatment is without risk, patients should not be exposed to avoidable risks when FDA-approved therapies are available.

Patients deserve treatments that are supported by evidence, manufactured under appropriate standards, and accompanied by clear information regarding their risks and benefits. Permitting compounding by 503B outsourcing facilities for any reason other than medical necessity puts patients at unnecessary risk and threatens consumer trust in the rigorous, evidence-based FDA approval framework.

For these reasons, we respectfully urge FDA to finalize its proposal and decline to add semaglutide, tirzepatide, and liraglutide to the 503B bulks list.

Sincerely,

- AiArthritis
- Alliance for Safe Biologics Medicines
- Alliance for Women's Health and Prevention
- Alliance of Sleep Apnea Partners
- American Association of Clinical Endocrinology (AACE)
- American Medical Women's Association
- American Society for Metabolic and Bariatric Surgery
- Association of Diabetes Care & Education Specialists
- Axis Advocates
- Collaborative for Evidence-Based Medicines (CEBM)
- Center for Patient Advocacy Leaders (CPALs)
- Color of Gastrointestinal Illnesses (COGI)
- Diabetes Leadership Council
- Diabetes Patient Advocacy Coalition
- DownPat Consulting
- Endocrine Society
- Gerontological Society of America
- Harmony Wellness Center

- Hermansky-Pudlak Syndrome Network
- HERmedicine/Ms.Medicine
- ICAN, International Cancer Advocacy Network
- Johns Hopkins Bloomberg School of Public Health
- League of United Latin American Citizens (LULAC)
- Let's Talk About Change
- Men's Health Network
- National Hispanic Medical Association (NHMA)
- Neuropathy Action Foundation
- Nevada Chronic Care Collaborative
- NOVA ScriptsCentral
- Obesity Medicine Association
- Preventive Cardiovascular Nurses Association
- Real Solutions Group
- Rep. Kim Schofield, Georgia General Assembly
- Reumatologo
- Shercare Senior Care
- StopAfib.org, Division of the American Foundation for Women’s Health
- The Obesity Society