



December 18, 2024

Submitted via Regulations.gov
Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Response to Citizen Petition Docket No. FDA-2024-P-5378

The Alliance for Pharmacy Compounding, representing more than 5,000 compounding professionals nationwide, and the National Community Pharmacists Association, representing 18,900 independent community pharmacies, submits this response in opposition to the Citizen Petition filed by Novo Nordisk Inc. (NNI), dated November 13, 2024, requesting the addition of semaglutide to the Demonstrably Difficult to Compound (DDC) lists under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FDCA). We strongly oppose this petition for the following reasons:

1. The DDC list framework is not finalized

The DDC list under Sections 503A and 503B has not been formally finalized by the FDA, making this request premature. While nominations to these lists have been accepted for review, no regulations or definitive criteria for inclusion have been issued for a final rule. Placing semaglutide on a list that lacks a formal regulatory framework would not only be procedurally inappropriate but also sets a concerning precedent.

2. Compounding semaglutide is routine pharmacy practice

The assertion that compounding semaglutide is inherently complex or difficult is baseless. Compounding semaglutide injections involves preparing an aqueous solution—a process that compounding pharmacists have successfully executed for decades for a variety of medications, including other peptides. The skills and expertise required for such preparations are fundamental to the profession and well within the scope of routine compounding practices.

3. Addressing a critical public health need

Semaglutide remains on the FDA's Drug Shortage List due to unprecedented demand generated in part by drugmakers' own aggressive marketing. During this shortage, compounding

pharmacies have ensured patients access to this drug, providing reliable and high-quality preparations and filling a gap that the drugmakers themselves have been unable to meet. Prohibiting access to compounded semaglutide while the shortage persists would exacerbate the health challenges faced by millions of Americans who depend on this life-enhancing medication.

4. Synthetic semaglutide API is safe and reliable

Novo Nordisk's concerns about synthetic semaglutide active pharmaceutical ingredients (API) are unfounded. Synthetic APIs are sourced from FDA-registered manufacturers and accompanied by certificates of analysis that verify identity and quality. Moreover, synthetic peptide APIs often demonstrate a more favorable impurity profile compared to recombinant APIs, as even Novo Nordisk's own data reveal. The FDA has already deemed synthetic semaglutide APIs appropriate for use in Abbreviated New Drug Applications (ANDAs), further confirming their reliability and adequacy for use.

5. Existing regulatory standards ensure patient safety

Compounded medications are already governed by robust state and federal regulations, including cGMP for 503B outsourcing facilities and USP <795> and <797> for 503A compounding pharmacies. These include strict standards for sterility, potency, and overall quality. The preparation of semaglutide injections adheres to these established guidelines, ensuring compliance with quality and regulatory standards. Assertions about bioavailability or variability in compounded semaglutide lack evidence and are counter to the experiences of prescribers and patients who continue to use these compounded products successfully.

6. No evidence of elevated public health risks

Novo Nordisk's assertions about adverse event data from the FDA's Adverse Event Reporting System (FAERS) fails to establish a causal link between compounded semaglutide and the reported events. In fact, the adverse events attributed to compounded semaglutide mirror the known side effects of FDA-approved semaglutide products. The adverse events attributed to the manufactured GLP-1 medications in the FEARS database also do not mean that those products are unsafe. Moreover, compounded semaglutide has been widely and successfully used throughout the shortage, with prescribers continuing to request it and patients reporting satisfaction with its effectiveness.

7. Motivations of the Citizen Petition are questionable

The timing of this petition, more than thirty months into the semaglutide shortage, raises questions about its motive. Rather than reflecting genuine patient safety concerns, it appears to be an effort to restrict compounding pharmacies' ability to meet patient needs, which the drugmaker incorrectly views as competition. Such actions undermine the trust patients place in both healthcare providers and regulatory processes.

Conclusion

Compounding semaglutide is a routine, well-established process that ensures patient access during a prolonged drug shortage. The DDC list framework is not finalized, making any addition premature. The claims in Novo Nordisk's Citizen Petition are speculative and unsupported by evidence, and their approval would unjustifiably limit access to a critical medication. APC strongly urges the FDA to reject this petition.

Thank you for considering our comments. APC and NCPA welcome the opportunity to discuss this matter further.

Sincerely,

Alliance for Pharmacy Compounding
National Community Pharmacists Association

The Alliance for Pharmacy Compounding is the industry trade association and the voice for pharmacy compounding and, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.