



Compounding the Joy of Living[®]



December 16, 2024

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Docket No. FDA-2015-N-0030 – Opposition to Novo Nordisk and Eli Lilly’s Requests to Place GLP-1 Medications on the Demonstrably Difficult to Compound List

Dear Commissioner Califf:

The undersigned organizations write to express our strong opposition to requests from Novo Nordisk and Eli Lilly to place semaglutide and tirzepatide on the 503A and 503B “Demonstrably Difficult to Compound” (DDC) lists. The requests are unwarranted, particularly given the millions of doses of compounded GLP1s that have been dispensed to meet patient need during the past 24+ months the brand-name products have been in severe shortage.

GLP-1 medications, as compounded by state-licensed compounding pharmacies following USP guidelines and state laws and outsourcing facilities adhering to cGMP, are demonstrably *not* difficult to compound. The compounding process for these medications is straightforward and well-documented, requiring only a few key ingredients and following established quality assurance protocols. Compounding pharmacies use validated procedures to ensure each medication's quality, including sterility and endotoxin testing, in addition to other quality checks.

Furthermore, the adverse event profiles for compounded versions of GLP-1 medications align closely with those of the branded drugs, suggesting that the adverse events are related to the drugs themselves and not the way they are produced. Legitimate compounded GLP-1 medications have been prepared with scrupulous care to support patients who otherwise face limited or no access to these therapies.

During this ongoing shortage, compounded GLP-1 medications have become for many patients a lifeline, providing treatment while the commercial products have been demonstrably unavailable. Adding GLP-1 receptor agonists to the DDC list would not only restrict access to

these essential medications but also place undue limitations on the ability of compounding pharmacies to meet the health needs of patients.

For these reasons, we respectfully urge the FDA to reject requests to place GLP-1 medications on the Demonstrably Difficult to Compound list. Compounded versions of these medications are a viable and necessary alternative during a time of critical need and restricting their access will only further hinder patient care.

Thank you for your consideration of our shared concerns. We stand ready to work with the FDA to ensure that compounded medications continue to serve as a vital healthcare option, especially during times of shortage.

Sincerely,

Alliance for Pharmacy Compounding

National Community Pharmacists Association