



November 15, 2024

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2015-N-0030 for Compounding of Human Drug Products Under the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket**

The Outsourcing Facilities Association ("OFA") is the trade association representing FDA-registered outsourcing facilities ("503Bs") operating pursuant to Section 503B of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). OFA's members provide compounding and repackaging services to patients, healthcare providers, and healthcare facilities, and strive to ensure the specific needs of both providers and patients are met with safe and effective compounded and/or repackaged medications under the current Good Manufacturing Practices ("cGMP") standards and guidance of the FDA. OFA has been actively following U.S. Food and Drug Administration's (the "FDA") implementation of the Compounding Quality Act<sup>1</sup> ("CQA") and has brought together members of industry to advocate for a safe, reasonable and practical application of the CQA.

OFA respectfully submits this comment to demonstrate the continued and ongoing drug shortage of semaglutide injection in the United States. The Federal Food, Drug, and Cosmetic Act defines the term "drug shortage" to mean "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2).

OFA conservatively estimates that outsourcing facilities are currently supplying 2 million American patients with semaglutide, based on reports by market participants.

Further, OFA conservatively estimates that roughly 80 million prescriptions for semaglutide were fulfilled with compounded semaglutide in the last 12 months, inclusive of 503A pharmacy compounders and 503B outsourcing facilities. These compounded products are fulfilling demand that is not being fulfilled by the manufacturer. Absent a demonstration by the manufacturer that it can readily supply more than 80 million prescriptions, semaglutide remains in drug shortage.<sup>2</sup>

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<sup>1</sup> Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (codified at 21 U.S.C. § 353b)

<sup>2</sup> OFA is also highlighting misinformation on the safety of compounded drug products. See CNN, "Compounded semaglutide associated with at least 10 deaths, Novo Nordisk CEO warns" (Nov. 10, 2024); *see also*, Citizen Petition from Covington & Burling LLP on Behalf of Novo Nordisk Inc., FDA Docket: FDA-2024-P-4937 (Oct. 21, 2024) ("Based on data available as of June 30, 2024, the FDA Adverse Event Reporting System (FAERS) reported 542 cases of adverse events associated with compounded "semaglutide" since 2018."). Even though Covington & Burling LLP on Behalf of Novo Nordisk Inc., certified that all information and views on which the Citizen Petition relies, and that it includes representative data and information known which are unfavorable to the Citizen Petition, Covington & Burling LLP on Behalf of Novo Nordisk Inc failed to report the complete FAERS data for

In 2020, the U.S. Census Bureau counted 331.4 million people living in the United States; more than three-quarters (77.9%) or 258.3 million were adults.<sup>3</sup> According to the CDC, during August 2021–August 2023, the prevalence of obesity in adults was 40.3%, or about 104 million patients.<sup>4</sup> We provide these estimates to show how conservative OFA’s estimates are of the current unmet medical need compounders are fulfilling for semaglutide. According to the manufacturer, “ongoing scaling efforts has supported a tripling of GLP-1 patient reach to ~11.5m over the past 3 years.”<sup>5</sup> Unless the manufacturer has scaled its supply of semaglutide by a factor of 10, the data supports that currently there exists a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.

According to the manufacturer’s CEO on November 6, 2024:

- "There's a **one-to-one relationship between script data and supply** and we believe that with more supply into the U.S. market that is going to lift the performance in the U.S.”
- "You will see that we will gradually be increasing the volume produced in the future like we've done in the past... We have **tripled volumes over the last three years.**"
- "**We still have a situation where there are far more patients who would like to have the treatment than what both Lilly and we can supply.**"<sup>6</sup> [emphasis added]

In other words, semaglutide remains in shortage.

Respectfully submitted,

/s Lee H. Rosebush, Chairman



semaglutide-containing products. As of November 8, 2024, a search of the FAERS database the database for “Ozempic”, “Rybelsus”, and “Wegovy” yields 12,602 reports. When “Semaglutide” as a fourth search term is added, the number of reports increased only to 13,215 reports. This data suggests that just 613 of the reports (<5%) are attributable to the compounding facilities, whereas 95% of reported adverse events in the FAERS database are attributable to branded drug product. This data is concerning considering the vast differences in product being supplied to the market based on the estimates contained herein as compared to Novo’s own statements having reached only 11.5 million patients over the last 3 years.

<sup>3</sup> Ogunwole, Stella et al. US Adult Population Grew Faster Than Nation’s Total Population From 2010 to 2020. United States Census Bureau. Table 1. Population by Age Group, <https://www.census.gov/library/stories/2021/08/united-states-adult-population-grew-faster-than-nations-total-population-from-2010-to-2020.html>

<sup>4</sup>Emmerich, Samuel et al. Obesity and Severe Obesity Prevalence in Adults: United States, August 2021 – August 2023. NCHS Data Brief, No. 508, September 2024, <https://www.cdc.gov/nchs/products/databriefs/db508.htm#:~:text=During%20August%202021%E2%80%93August%202023%2C%20the%20prevalence%20of%20obesity%20in,39%20and%2060%20and%20older.>

<sup>5</sup> Novo Nordisk. Novo Nordisk has tripled its global GLP-1 patient reach and increased its GLP-1 volume market share to 65% in 3 years. Investor Presentation. First 9 months of 2024, <https://investor.novonordisk.com/q3-2024-presentation/?page=11>

<sup>6</sup> Gronholt-Pedersen, Jacob et al. Novo Nordisk CEO on Wegovy prices, supplies and compounding. Reuters. November 06, 2024, <https://www.reuters.com/business/healthcare-pharmaceuticals/novo-nordisk-ceo-wegovy-prices-supplies-compounding-2024-11-06/>