Published on *The National Law Review* https://natlawreview.com

GLP-1 Drugs: FDA Removes Semaglutide from the Drug Shortage List

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On February 21, 2025, the U.S. Food and Drug Administration (FDA) issued a Declaratory Order determining that the semaglutide drug shortage has been resolved. The timing of this order was unexpected due to the ongoing litigation between FDA and the Outsourcing Facilities Association (OFA) involving tirzepatide, though the decision was not. Our prior blog "GLP-1 Drugs: FDA Sued Over Removing Tirzepatide from the Drug Shortage List" discusses the litigation. On February 24, 2024, OFA initiated a similar action against FDA challenging the removal of semaglutide from the drug shortage list.

***FDA's Declaratory Order*:** FDA's 13-page order describes the process that FDA undertook to come to this conclusion and explains that FDA obtained information both from the manufacturer (Novo Nordisk) as well as from patients, health care providers, and others, including compounders. FDA concluded that based on the available evidence, that the supply of semaglutide "meets or exceeds current demand, and that, based on our best judgment looking at the available information with its limitations, supply will meet or exceed projected demand."

FDA acknowledges in the Declaratory Order that:

> [E]ven when a shortage is considered resolved, patients and prescribers may still see intermittent localized supply disruptions as products move through the supply chain from the manufacturer and distributors to local pharmacies.

Current Status of Compounding of Semaglutide: With respect to the current status of compounding of semaglutide, FDA noted that it wished to "avoid unnecessary disruption to patient treatment," and outlined the current enforcement policy moving forward:

> [T]he agency does not intend to take action against compounders for violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) arising from conditions that depend on

semaglutide injection products' inclusion on FDA's drug shortage list:

- For a state-licensed pharmacy under section 503A of the FD&C Act compounding, distributing or dispensing semaglutide injections within 60 calendar days from today's announcement, until **April 22, 2025**.
- For outsourcing facilities under section 503B compounding, distributing or dispensing semaglutide injections within 90 calendar days from today's announcement, until **May 22, 2025**.

FDA may still take action regarding violations of any other statutory or regulatory requirements, such as to address findings that a product may be of substandard quality or otherwise unsafe.

In addition to the Declaratory Order, FDA also published an update to its website entitled "FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize." This update also included FDA's enforcement policy described above, as well as stated that although dulaglutide remains "in shortage", the manufacturers have reported all presentations are available. Liraglutide is also still in shortage, but the manufacturer has reported two presentations are available but three have limited availability. Finally, FDA notes that "[w]hen a status is noted as 'available,' that reflects the most current information from the manufacturer but is not an FDA determination that the shortage has been resolved."

In the ongoing case with the OFA involving tirzepatide, the parties are currently filing briefs on the Plaintiff's motion for preliminary injunction. Briefing will be completed on February 25, 2025. We expect the Court to rule on the motion sometime in March. Depending on the Court's ruling, the outcome could have an impact on the continued availability of semaglutide as well.

On Monday, February 24, 2025, OFA filed a lawsuit against FDA in Fort Worth Texas over FDA's decision to remove semaglutide from the drug shortage list. The lawsuit claims the FDA's finding that there was no longer a shortage of semaglutide was arbitrary and capricious. We expect this case to proceed on a similar track as tirzepatide and the cases may be consolidated.

Key Takeaways*.* FDA's determination to remove semaglutide from the drug shortage list is not surprising. The only surprise here is the timing. Compounding of semaglutide will continue until at least **May 22, 2025,** for 503B Pharmacies (also known as 503B Outsourcing Facilities, which are compounding pharmacies that can produce large batches of medications without patient-specific prescriptions). Whether it will extend beyond that timeframe will depend on the outcome of the OFA litigation and FDA's reaction to the case.

It will also be very interesting to watch developments on certain GLP-1 products that continue to be compounded under the rationale that certain compounded products are required to meet the individual needs of patients. There are a number of different doses, different dosage forms, and combination of ingredients being compounded, and FDA has not yet taken a position with respect to these compounded products.

Want To Learn More? *See our prior blogs.*

- FDA Targets GLP-1 Providers with Warning Letters
- GLP-1 Drugs: FDA Removes Lilly's Zepbound® and Mounjaro® (semaglutide injection) from

its Drug Shortage List
- GLP-1 Drugs: Brand Companies Push FDA to Limit Compounding

National Law Review, Volume XV, Number 56