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FDA removes semaglutide from drug shortage list

Key takeaways:

- An update to the FDA drug shortage list on Feb. 21 listed the semaglutide shortage as being resolved.
- In a press release, Novo Nordisk said it is shipping all doses of the medication regularly to wholesalers.

The FDA has removed semaglutide from its drug shortage list after the agency determined the current supply of the drug can meet present and future demand, Novo Nordisk and the FDA announced.

On Feb. 21, the FDA updated its drug shortage list and labeled the shortage of all doses of injectable semaglutide (Ozempic/Wegovy) as being resolved. The update was confirmed in a press release by Novo Nordisk, which stated the company continues to ship all doses of semaglutide regularly to wholesalers following investments to increase its manufacturing capacity.

On Feb. 21, the FDA removed all doses of semaglutide from its drug shortage list.

one should have to compromise their health due to misinformation and reach for fake or illegitimate knock-off drugs that pose significant safety risks to patients. Patient safety remains our top priority and, in line with our purpose to improve lives and health, we continue to partner, educate, and advocate for expanded, affordable access to our medicines for those who need and rely on them."

As Healio previously reported, semaglutide was added to the FDA shortage list in early 2022. Its placement on the drug shortage list allowed compounding pharmacies to manufacture semaglutide, as the FDA did not consider the drug to be "commercially available" in the U.S.

The FDA announced it will allow companies to continue dispensing compounded semaglutide for up to 90 more days. State-licensed pharmacies and physicians compounded under section 503A of the Federal Food, Drug and Cosmetic Act can continue compounded and distributing semaglutide until April 22, and outsourcing facilities under section 503B of the law are permitted to dispense compounded semaglutide until May 22. The agency stated the deadlines were set "to avoid unnecessary disruption to patient treatment."

Semaglutide's removal from the drug shortage list comes about 2 months after the FDA also confirmed that the shortage of tirzepatide (Mounjaro/Zepbound, Eli Lilly), another incretin-based drug for treating type 2 diabetes and obesity, was resolved. As part of that announcement, the FDA stated it would continue to allow compounded forms of the drug to be manufactured or distributed by state-licensed pharmacies through Feb. 18 and by outsourcing facilities through March 19.

During the shortage, the FDA has issued multiple warnings about using off-brand semaglutide. In December 2023, the FDA announced counterfeit forms of semaglutide were circulating through the U.S. drug supply chain and asked consumers to check lot numbers to make sure they were using an authentic form of the drug. In February 2024, the agency sent warning letters to two companies for offering unapproved and misbranded forms of semaglutide and tirzepatide on their websites. In July 2024, the FDA warned patients about potential adverse events linked to some compounded forms of semaglutide due to dosing errors.

The removal of semaglutide from the drug shortage list comes as public officials raise concerns about counterfeit and illegal forms of diabetes and obesity medications entering the U.S. On Feb. 19, the National Association of Attorneys General sent a letter to acting FDA commissioner **Sara Brenner, MD, MPH,** asking the agency to take steps to stop "bad actors" from profiting off the sale of counterfeit incretin-based drugs. The letter cited reports of counterfeit GLP-1s entering the U.S. from foreign countries, active ingredients of the drugs being sold illegally to consumers and compounding pharmacies that may be participating illegally in the market. The letter was signed attorneys general from 38 states and U.S. territories.

"Demand for the medications Mounjaro, Zepbound, Ozempic and Wegovy has skyrocketed, but supply shortages and high costs have created opportunities for wrongdoers to cash in and endanger consumers," the organization stated in its letter. "The FDA has the expertise and the resources to stop this conduct and better protect consumers."

References:

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