

Wegovy pill for weight loss gets green light from FDA

Novo Nordisk drug expected to be available within weeks

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Associated Press

U.S. regulators have approved a pill version of the blockbuster weight-loss drug Wegovy, the first daily oral medication to treat obesity.

The U.S. Food and Drug Administration's approval this week handed drugmaker Novo Nordisk an edge over rival Eli Lilly in the race to market an obesity pill. Lilly's oral drug, orlistat, is still under review.

Both pills are GLP-1 drugs that work like widely used injectables to mimic a natural hormone that controls appetite and feelings of fullness.

In recent years, Novo Nordisk's injectable Wegovy and Lilly's Zepbound have revolutionized obesity treatment globally and in the U.S., where 100 million people have the chronic disease.

The Wegovy pills are expected to be available within weeks, company officials said. Availability of oral pills to treat

obesity could expand the booming market for obesity treatments by broadening access and reducing costs, experts said.

About 1 in 8 Americans have used injectable GLP-1 drugs, according to a survey from KFF, a nonprofit health policy research group. But many more have trouble affording the costly shots.

"There's an entire demographic that can benefit from the pills," said Dr. Fatima Cody Stanford, a Massachusetts General Hospital obesity expert. "For me, it's not just about who gets it across the finish line first. It's about having these options available to patients."

The Novo Nordisk obesity pill contains 25 milligrams of semaglutide. That's the same ingredient in injectables Wegovy and Ozempic and in Rybelsus, a lower-dose pill approved to treat diabetes in 2019.

In a clinical trial, participants who took oral Wegovy lost 13.6% of their total body weight on average over about 15 months, compared with a 2.2% loss if they took a placebo, or dummy pill. That's nearly the same as injectable Wegovy, with an average weight loss of about 15%.

Participants in a clinical trial who took

the highest dose of Lilly's orlistat lost 11.2% of their total body weight on average over nearly 17 months, compared with a 2.1% loss in those who took a placebo.

Both pills resulted in less weight loss than the average achieved with Lilly's Zepbound, or tirzepatide, which targets two gut hormones, GLP-1 and GIP, and led to a 21% average weight loss.

All the GLP-1 drugs, oral or injectable, have similar side effects, including nausea and diarrhea.

Both daily pills promise convenience, but the Wegovy pill must be taken with a sip of water in the morning on an empty stomach, with a 30-minute break before eating or drinking.

That's because Novo Nordisk had to design the pill in a way that prevented the drug from being broken down in the stomach before it could be absorbed by the bloodstream.

By contrast, Lilly's orlistat has no dosing restrictions. That drug is being considered under the FDA's new priority voucher program aimed at cutting drug approval times. A decision is expected by spring.