

# Safety Notification

## PharmPix Clinical Department

*PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate the latest up-to-date drug safety information.*

### FDA Requests Removal of Suicidal Behavior and Ideation Warning from Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications

**U.S. Food & Drug Administration**  
**Publication Date:**

01/13/2026

**Drug Indication:**

Weight reduction in persons with obesity or overweight.

**Safety Topic:**

Removal of suicidal ideation and behavior warning from GLP-1 receptor agonist labeling.

It is for this reason that we are notifying you that on January 13, 2026, the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide)

#### Reason for Communication

The FDA is requesting that drug application holders remove information regarding the risk of suicidal ideation and behavior (SI/B) from the prescribing information of certain glucagon-like peptide-1 receptor agonist (GLP-1 RA) medications approved for weight management. This request follows a comprehensive FDA evaluation of clinical trial data, postmarketing reports, observational studies, and real-world evidence, which did not identify an increased risk of suicidal ideation or behavior associated with GLP-1 RA use.

At the time of original approval, labeling for these products included SI/B language in the Warnings and Precautions section based on observations with older weight-loss medications. Subsequent analyses, including a large meta-analysis of placebo-controlled clinical trials and a retrospective cohort study using the FDA Sentinel System, demonstrated no increased risk of suicidal ideation, suicidal behavior, or other psychiatric adverse events in patients treated with GLP-1 receptor agonists compared with placebo or active comparators. Based on the totality of evidence, the FDA determined that removal of this language is appropriate to ensure consistent, evidence-based labeling across all FDA-approved GLP-1 RA products.

#### Pharmacy Required Action

**Advise** patients that they should not discontinue GLP-1 RA therapy without contacting their health care provider. Educate patients that the FDA found no increased risk of suicidal ideation or behavior with GLP-1 RA use after an extensive review of available data.

**Assess** whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) by any of the following ways:

Complete and submit the [MedWatch Online Voluntary Reporting Form](#) online.

[Download](#) FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#).

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

REFERENCES:

1. U.S. Food and Drug Administration. (2026). *FDA Requests Removal of Suicidal Behavior and Ideation Warning from Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications.* <https://www.fda.gov/media/190557/download?attachment>