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PRESS RELEASE

# Wiley Helps Persuade FDA to Restrict Compounded Semaglutide Products

February 13, 2026

Wiley helped persuade the U.S. Food and Drug Administration (FDA) to restrict the use of GLP-1 ingredients in unapproved compounded products, a decision that will help protect consumers and has significant implications for the pharmaceutical and health care industries.

In an August 2025 citizens' petition on behalf of Adventa Pharma, Wiley urged the FDA to address the escalating public health risks associated with compounded GLP-1 products such as semaglutide, including clarifying guidance regarding the manufacture, risk assessment procedures, product misbranding, study mandates, and more. The petition argued that the large-scale production and distribution of compounded semaglutide products has risen beyond the traditional practice of customized pharmacy compounding, and that these products are a danger to public health. Specifically, the Petition highlighted concerns regarding the lack of immunogenicity risk assessments, the use of unapproved salt forms, and misleading "mass-marketing" practices.

On February 6, 2026, the FDA announced definitive new enforcement priorities. Commissioner Martin Makary stated the Agency's intent to "take decisive steps to restrict GLP-1 active pharmaceutical ingredients (APIs) intended for use in non-FDA-approved compounded drugs that are being mass-marketed." The Agency further affirmed it will use all available enforcement tools, including seizure and injunction, to address these violations.

Neal Seth, partner in the Intellectual Property Practice, filed the petition.

## Related Professionals

Neal Seth
Partner
202.719.4179
nseth@wiley.law

## Practice Areas

Food & Drug

Intellectual Property

Pharmaceuticals, Biologics, and Life Sciences