

Compounding the Joy of Living®

Statement from the Alliance for Pharmacy Compounding Celebrating FDA's Action Against Illegal Online Businesses

December 18, 2024

The Alliance for Pharmacy Compounding commends the U.S. Food and Drug Administration for taking decisive action against illegal online businesses marketing unapproved and improperly labeled peptide products, including those labeled as semaglutide, retatrutide, and other related compounds. This critical enforcement action highlights the ongoing threat posed by illegal sellers operating under the guise of "research-use only" while in fact endangering public health.

APC fully supports the FDA's efforts to protect patients by addressing these dangerous and deceptive practices. The cited companies have been marketing unapproved drugs to unsuspecting consumers, jeopardizing safety, quality, and trust.

We also emphasize the **important distinction** between these illegal operators and legitimate state-licensed compounding pharmacies. Legitimate compounding pharmacies adhere to rigorous state and federal regulations and national compounding standards, ensuring that medications are prepared safely, accurately, and exclusively for patients based on valid prescriptions from licensed healthcare providers.

"Actions like these taken by FDA are necessary to uphold public safety and restore confidence in healthcare," said Tenille Davis, PharmD, Chief Advocacy Officer for APC. "There's simply no comparison between unregulated online sellers of so-called 'research-use only' products and legitimate compounding pharmacies, which operate within strict legal and professional guidelines to meet critical patient needs."

The FDA's enforcement against illegal sellers sends a clear message: patient safety cannot be compromised. APC encourages prescribers and patients to verify that they are working with legitimate, state-licensed compounding pharmacies. Resources such as APC's **Is It Legit?** website (a4pc.org/isitlegit) offer a quick and effective tool for confirming a pharmacy's credentials.

We look forward to continued collaboration with the FDA to safeguard patient access to highquality compounded medications while rooting out bad actors who threaten public health. The Alliance for Pharmacy Compounding is the industry trade association and the voice for pharmacy compounding and, representing more than 600 compounding small businesses — including compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

In traditional compounding, pharmacists create a customized medication, most often from pure ingredients, for an individual patient pursuant to a prescription. Pharmacists' ability to compound medications is authorized in federal law and for good reason: Manufactured drugs don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient or the appropriate FDA-approved drug is not commercially available.

Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.