FDA Turns Up the Heat on GLP 1 Dupes Sold “For Research Use Only,” Finds Intended Use Suggests Otherwise

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Consumer demand for GLP-1 drugs such as Ozempic and Zepbound continues to surge, fueling rapid growth in the market for GLP-1 drugs and compounded GLP-1 products, as well as supplements that are marketed to have similar effects. (See our prior post on the supplement trend here.) Most recently, FDA has turned its attention to an emerging problematic approach to capitalizing on demand for GLP-1 products: the direct-to-consumer sale of unapproved injectable GLP-1 dupes. Specifically, FDA issued seven warning letters this week to companies selling more than 20 violative products directly to consumers. Five of the cited companies marketed injectable GLP-1 dupes “for research use only” and “not for human consumption,” despite website content demonstrating the products were intended to be used as drugs. FDA determined these injectables were unapproved new drugs under Section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). In its latest warning letters, FDA’s position is unequivocal: selling unapproved, injectable GLP-1 dupes to consumers under the guise that the products are for “research use only” violates FDA regulations and may pose serious health risks.

Beyond selling injectables marketed as Tirzepatide and Semaglutide, the companies also advertised newer and experimental GLP-1–like peptides, including Cagrilintide, which mimics amylin, a hormone with a different mechanism of action than FDA-approved GLP-1 receptor agonists, and Retatrutide, an investigational triple hormone receptor agonist that is still in clinical development.

These warning letters reinforce that labeling a product “for research use only” does not insulate a seller or manufacturer from enforcement when advertising and distribution demonstrate that a product is intended for use as a drug. Under longstanding FDA regulations and enforcement precedent, an article’s “intended use” is determined by the objective intent of the party responsible for its labeling and marketing (e.g., manufacturer, distributor, seller). While “objective intent” may seem narrow, FDA has broad discretion under its regulations to look beyond express statements and label claims to digital advertising, oral and written statements, as well as a product’s design or composition, or the circumstances surrounding a product’s distribution.

Here, FDA cited extensive evidence of the products’ intended use as drugs, including claims such as “Uses: Weight Loss,” detailed dosing instructions (e.g., “Start: 0.25 mg weekly; titrate up to 2.5 mg weekly”), claims about appetite suppression and satiety, and statements highlighting results on randomized controlled clinical trial data. FDA also noted that the companies sold Bacteriostatic Water alongside the peptide products. Because Bacteriostatic Water is used to dilute or reconstitute medications that are administered by injection, offering these products in tandem further supported

FDA’s conclusion that the products were intended for use as drugs.

Unlike dietary supplements, injectable drug products are subject to more stringent FDA safety, manufacturing, and approval requirements. Because these products are unapproved, FDA cannot verify their safety, effectiveness, or compliance with Current Good Manufacturing Practice (CGMP) standards. As a result, the products’ identity, potency, quality, and purity cannot be assured. FDA emphasized that unapproved injectable drugs are particularly concerning because injectables are delivered directly into the body—sometimes directly into the bloodstream—bypassing many of the body’s natural defenses against contaminants, impurities, and microorganisms. Accordingly, manufacturing deficiencies, sterility failures, or dosing errors can lead to serious and potentially life-threatening outcomes.

These warning letters reflect FDA’s ongoing enforcement against GLP-1 dupes and products seeking to capitalize on the demand for GLP-1s in novel ways. Companies in this market should expect continued scrutiny and recognize that labeling products “for research use only” does not provide a safe harbor from FDA requirements.