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## **Regulatory Restrictions/Complications for Compounding Semaglutide**

### **Requirements for Compounded Ingredients:**

Under federal law (Section 503A), to be eligible for use in a compounded product, an active ingredient must meet one of the following criteria:

1. Be an active ingredient in an FDA-approved drug product.
2. Have a USP or National Formulary drug monograph.
3. Appear on the Section 503A Interim or Final Bulks List published by FDA.

Additionally, peptides must not be classified as a biologic (defined as greater than 40 amino acids) in order to be compounded in a traditional compounding pharmacy.

Semaglutide (the chemical ***base form***) is found in an FDA-approved drug product (ie. Wegovy). Semaglutide is also a relatively small molecule and therefore is not classified as a biologic. HOWEVER, Semaglutide (base form) for injection is patent protected at this time. This means the only legal way to obtain and compound with the ingredient is to use the FDA-approved drug product. Additionally, there are restrictions for compounding products that deemed "essentially copies of patented drugs", unless the drug is listed on the FDA drug shortage list. If the drug is on shortage, then obtaining it legally to compound a preparation is not an option since the ingredient is not available.

*Why are some pharmacies promoting they can compound Semaglutide and what exactly are they preparing?*

These pharmacies are likely violating at least one regulation, either in their drug product selection or patent protection. Most of these pharmacies are compounding with **Semaglutide Sodium (a salt form of the chemical)**. The salt form does **NOT** meet any of the 3 federal law requirements. Additionally, the only supplier that we are aware of selling this salt form ingredient is one that we refuse to purchase chemicals from due to a history of poor quality products and sketchy business operations. All of our high-quality suppliers for our compounding ingredients do not stock the ingredient due to the regulatory restrictions. Additionally, pharmaceutical companies are sending cease and desist letters and threatening legal recourse to pharmacies that may be violating their patent.

If you have additional questions, please contact Bryan Ziegler, PharmD, MBA at 843.665.0289.