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Via E-Mail: arvindmd@regentherapy.com
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Arvind Chakravarthy
Josh Stone

Re: Legal Opinion on the Sale of Peptides in a Clinic Setting

Dear Arvind:

Thank you for the opportunity to work on this project. Pursuant to your request, I have prepared the following opinion letter. In preparing this opinion, I have reviewed the federal regulatory frameworks applicable to the wholesale of research-grade peptides ("RGP") to be labeled **'Physician Use Only'** and then retailed in a clinical setting where a licensed medical provider works. This opinion provides an overview of current legal considerations and outlines a recommended compliance process for ZenLabs Wholesale ("ZenLabs") to stock and provide peptides in a manner consistent with a good faith effort to adhere to existing regulations.

Please note that this opinion only applies to the current state of the law and regulations. Specific state laws or regulations impacting RGPs should be reviewed separately as a supplement to the following material. Moreover, this opinion is being issued to and solely for the benefit of ZenLabs. Nothing in this letter is intended to advise any other person firm or entity.

I have reviewed several sources and the nature of RGP wholesales to clinics remains in flux at this time. Consequently, I recommend that ZenLabs conduct a quarterly review for the next year to stay abreast of any changes or developments to current regulations and legal guidance. Thereafter, I would recommend that bi-annual reviews be conducted until the regulations and legal guidance is more settled. Obviously, any material developments in between these reviews will be noted and discussed as appropriate.

Summary of Opinion

Purchasing RGPs by individuals is not prohibited by federal law. Selling RGPs labeled "Physician Use Only" is likewise not prohibited by federal law. However, as noted the clinic environment introduces additional considerations that require special precautions to avoid misinterpretation, misuse or agency review.

To avoid such problems, processes should be implemented regarding proper labeling, marketing restrictions, waivers and releases, staff training and maintaining separations separation from medical

To avoid such problems, processes should be implemented regarding proper labeling, marketing restrictions, waivers and releases, staff training and maintaining separations separation from medical services.

1. Federal Regulatory Considerations

The FDA regulates peptides as drugs or biologics under the Federal Food, Drug, and Cosmetic Act (FDCA) if they are intended to diagnose, treat, or affect body function (21 U.S.C. § 321(g)(l)). However, peptides labeled clearly 'Physician Use Only' and sold without therapeutic claims fall outside FDA enforcement jurisdiction.

2. Key federal compliance factors:

   a. Labeling must state "Physician Use Only" but need not be labeled "Not for Human Consumption." If the purchaser is advised to seek medical advice from their doctor and no comments about the peptide's ability to treat or cure disease or illness is made, the use of this label should be given serious consideration. The Physician Use Only label simply illustrates but refers to the peptide's intended use within a clinical setting, as an FDA-approved prescription medication, for off-label use by a physician, or as a compounded medication prepared under a physician's supervision. The specific labeling depends on the peptide's regulatory status and how it is prescribed or dispensed.

   b. No marketing materials or verbal communication may include health or therapeutic claims; however, it is permissible for staff and providers to share information and studies about results that other patients have experienced. For Example:

      1. Staff including licensed providers can site a study that shows the common effects of a Peptide such as improved recovery, improved endurance or fat loss.

      2. Staff including licensed providers cannot say, this peptide will improve recovery and heal your ligaments and tendons.

   c. This area of compliance includes proper labeling as a way to get around FDA regulation and rules. According to an article in BioSpace dated December 25, 2025:

      > The FDA last week issued warning letters against a handful of companies flagging violations regarding the promotion and sale of unapproved weight-loss drugs, including unlicensed versions of the blockbuster therapies semaglutide and tirzepatide.
      >
      > The warnings, dated December 10, were issued to Prime Peptides, Summit Research Peptides, Swisschems and Xcel Research, all of which were found to be selling unapproved GLP-1 treatments that, despite being labelled as for research purposes, were marketed for human use.
      >
      > The FDA looked through the websites and social media pages of the four companies and found evidence that they were positioning their knock-off GLP-1 products "to prevent,

treat, or cure disease conditions and/or affect the structure or function of the body," the regulator wrote in all four warning letters.

Such claims, according to the agency, are in violation of the Federal Food, Drug, and Cosmetic Act, which prohibits the sale of unapproved drugs. "This letter is not intended to be an all-inclusive statement of violations that exist in connection with your products," the FDA wrote in its warning letters, noting that the companies are responsible for investigating and resolving all violations.

The interesting and notable fact is that each of these online distributors were speaking "out of both ends of their mouths". By actually marketing their products to address specific medical conditions despite properly labeling them as "For Research Purposes Only" was determined to be a "ruse." Consequently, when putting together any process for marketing or sale one must be mindful that if there is a review by the FDA, the agency will be looking for evidence that distributor is explicitly or implicitly promoting their product for therapeutic or medicinal use. However, this issue is largely addressed if a physician is prescribing or being consulted on the use of the RGPs.

In light of the foregoing, staff must be trained not to offer advice that could be construed as medical or suggest a curative or therapeutic benefit specific to that patients' symptoms.

3. Clinic-Specific Compliance Risks

Selling peptides within a clinic setting, which is inherently associated with healthcare services, increases the risk that consumers may interpret such sales as having medical endorsement. To mitigate this:

1. Licensed provider and staff may discuss known benefits of peptides.

2. Licensed provider and staff may not tell a patient of a specific benefit to address a specific symptom they are experiencing or want to improve.

4. State Law Considerations

While federal compliance is critical, state-level regulation also applies. For example, California's Proposition 65 mandates warnings for substances linked to cancer or reproductive harm. Other states may impose labeling, advertising, or product-specific requirements that must be reviewed based on your operating jurisdictions.

Jurisdiction-specific legal review is recommended for all states in which peptides will be sold or distributed.

5. Waiver and Risk Mitigation

Your current waiver provides a solid foundation. It disclaims therapeutic use, requires purchaser acknowledgment of risk, and affirms legal intent. It is important to note that ***the purchase of these products is not illegal.*** If distributed in accordance with FDA regulations and regulatory guidance, the purpose to which the purchaser puts the product is cannot be controlled by the distributor. However, distributors should be watchful for facts or circumstances that their product will be used in a prohibited

manner thereby giving the distributor constructive knowledge of misuse.

6. Recommended Compliance Process for Clinic-Based Peptide Sales

To operate in a legally defensible manner, ZenLabs should adopt the following process:

A. Inventory and Labeling

1. Stock only peptides labeled "Physician Use Only"

B. Marketing and Display

1. Display peptides in a retail or administrative area distinct from patient treatment spaces.

2. Reference guidance to third parties may be provided to patients for their own information, research and review. The use of a QR code to accomplish this task is permissible. I would recommend such a code be added to the waiver and release.

C. Sales Protocol

1. Require all purchasers to sign a waiver and disclosure form. This form should be reviewed on a regular basis to ensure it is up to date.

2. Verify age of patient is over 18 and confirm purchaser understanding of the waiver and disclosure f01m.

D. Staff Training

1. Train all employees involved in peptide sales on the impo1iance of nontherapeutic positioning.

2. Monitor compliance through periodic internal reviews.

E. Ongoing Legal Oversight

1. Regularly review ‘state specific’ regulations.

2. Monitor FDA guidance and enforcement actions.

Conclusion

Based on current law and regulatory interpretations, ZenLabs may sell peptides in its clinic labeled for Physician Use Only. A defined protocol that separates product sales from medical services, supported by clear disclaimers and enhanced waivers, will demonstrate a good faith effort to comply with applicable laws.

This letter is intended as a legal opinion based on current information and does not constitute a guarantee against enforcement or liability. Continued legal monitoring and procedural compliance are recommended.

Sincerely,

/s/ Shawn D. Twing

Shawn D. Twing,
Attorney and Counselor at Law, PLLC