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June 19, 2025

VIA EMAIL (ben@nutrastrips.com)

Lionheart Enterprises, LLC  
12411 South 265 West, Unit C  
Draper, Utah 84020  
Attn: Benjamin Bartel

**Re: Peptides in Oral Strips**

Dear Mr. Bartel:

You have asked us to answer the broad question of whether you may manufacture your oral strips to contain peptides. Under the Dietary Supplement Health and Education Act ("**DSHEA**"), 21 U.S.C. § 321(ff), a "dietary supplement" is a product intended to supplement the diet that contains one or more of the following "dietary ingredients":

- A vitamin;
- A mineral;
- An herb or other botanical;
- An amino acid;
- A dietary substance for use by man to supplement the diet by increasing the total dietary intake;
- A concentrate, metabolite, constituent, extract, or combination of the above.

The product must be intended for ingestion, not represented as conventional food, and must be labeled as a dietary supplement. Thus, the question becomes whether peptides are "dietary ingredients" under DSHEA.

Peptides are chains of amino acids, which are themselves recognized dietary ingredients under 21 U.S.C. § 321(ff)(1)(D). Peptides derived from natural sources (e.g., collagen peptides, whey protein hydrolysates) are commonly sold as dietary supplements and generally fall within the scope of the statute since:

- They are intended to supplement the diet;
- They are ingested orally; and
- They are not represented as drugs.

While long-chain or pharmacologically active synthetic peptides (e.g., semaglutide, BPC-157) may have biological activity, their classification depends on both intended use and regulatory precedent.



The intended use of the product – based on labeling, marketing, and claims – determines its classification. If the product is marketed to diagnose, treat, cure, or prevent disease, it is a drug under 21 U.S.C. § 321(g)(1)(B). If marketed with structure/function claims (e.g., “supports joint health,” “enhances muscle recovery”), and avoids disease claims, it may be marketed as a dietary supplement. Thus, the same orally consumed peptide may be a supplement or a drug depending solely on claims and intended use.

On the other hand, a peptide cannot be marketed as a dietary supplement if it was previously approved as a drug, or was authorized for investigation as a new drug or biologic under an IND before it was marketed as a dietary supplement, unless the FDA issues a regulation allowing it (21 U.S.C. § 321(ff)(3)(B)).

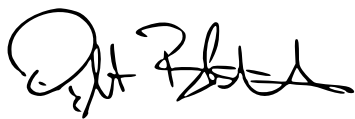
Finally, in accordance with FDA guidance, a dietary supplement must be intended for ingestion. Orally dissolving strips, capsules, tablets, and powders are typically compliant, while sublingual, transdermal, or injectable routes are not recognized for dietary supplements. A peptide delivered in an oral strip that dissolves in the mouth and then is swallowed would generally meet the ingestion requirement.

We have reviewed the list of products on your website ([nutrastrips.com](http://nutrastrips.com)) and have confirmed that they are dietary supplements, are marketed as such, and would be covered by the opinions expressed in this letter.

This opinion is given as of the date first written above solely for your benefit in connection with the question posed and may not be delivered to, quoted or relied upon by any persons other than you, or for any other purpose, without our prior written consent. We assume no obligation to advise you of facts, circumstances, events or developments which hereafter may be brought to our attention and which may alter, affect or modify the opinions expressed herein.

Very truly yours,

**BECKSTRAND LAW OFFICES**

A handwritten signature in black ink, appearing to read "Dwight Beckstrand". The signature is fluid and cursive, with a large initial "D" and "B".

Dwight Beckstrand, Esq.