CENTER FOR Science IN THE Public Interest
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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852

**Re: Pharmacy Compounding Advisory Committee Meeting on Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substance List (Docket No. FDA-2025-N-6895)**

Dear Dockets Management Staff,

Thank you for the opportunity to provide comments for consideration by the FDA's Pharmacy Compounding Advisory Committee.

The Center for Science in the Public Interest, an advocacy group that accepts no funding from industry, opposes the proposed inclusion of the seven bulk peptide drug substances (BPC-157, KPV, TB-500, MOTs-C, emideltide, semax, and epitalon) in the 503A Bulks List,[1] allowing them to be compounded, because this action is inconsistent with the FDA's own standards for pharmacy compounding, poses dangers to consumers, and removes incentives for developing new pharmaceutical products through the standard drug approval process.

Agency scientists recently reviewed the available data for these seven bulk drug substances in detail and recommended that all seven "NOT be included in the 503A Bulks List"[2] (emphasis in the original) because of the overall lack of data to characterize the substances' historical use, physical and chemical properties, safety profile, and effectiveness (Table 1). We support the career scientists' determinations and urge the committee and subsequently the agency itself to follow the recommendations of the FDA's own subject matter experts.

**Inclusion of these peptides on the 503A Bulks List is inconsistent with FDA's existing pharmacy compounding standards.**
The proposed addition of the seven peptides to the 503A Bulks List is inconsistent with the agency's own criteria established in 21 CFR 216.23 for allowing a bulk drug substance for use in compounding. These criteria are historical use of the substance in compounded drug products, physical and chemical characterization of the substance, any safety issues presented by the use of the substance in compounded drug products, and available evidence of effectiveness or lack thereof.[3]

FDA's scientific staff have used these criteria to assess the seven peptides and have concluded that none of these peptides sufficiently meet any of the four criteria when considered together (Table 1). With the exception of emideltide, which has been used in the past in compounding, FDA staff reviews found the data and published literature on the historical use of these peptides in compounding to be limited, unclear, and in some cases, unknown. The medical officers determined that all seven of the peptides are "not well-characterized from the physical and chemical characterization perspective." For all peptides under consideration, FDA medical officers concluded that there was "insufficient" or "a lack of" both safety and effectiveness information to support the substances for their proposed indications and routes of administration.

This dearth of data is clearly different from that supporting all of the bulk drug substances that are currently on the 503A Bulks List. These are all are supported by some efficacy data as outlined in the 2016 Proposed Rule, which was finalized in 2019.[4,5] The peptides under consideration at this meeting have more in common with oxitriptan, piracetam, silver protein mild, and tranilast, the four bulk drug substances the agency decided to exclude from the 503A Bulks List due to safety issues, lack of efficacy evidence, and/or existence of FDA-approved alternatives.[4] (Of course, all the FDA-approved products suitable for compounding have demonstrated evidence of safety and effectiveness.)

**These peptides do not have proven benefits and may harm consumers.**
Six of the seven peptides considered at this meeting are nominated for administration via injection (Table 1), a route of administration with well-documented safety risks including the potential for impurities and aggregation.[6] These risks will be harder to mitigate because compounded substances prepared by 503A compounding pharmacies are typically exempt from FDA's current good manufacturing practice (CGMP) requirements.[7] In contrast, most of the bulk drug substances currently on the 503A Bulks List are only allowed to be compounded for topical use.[3]

Moreover, agency scientists have identified FDA-approved treatments for all the medical conditions that the seven peptides are intended to treat (Table 1). For example, mesalamine and three other orally administered drugs are available to treat mild to moderate ulcerative colitis, in lieu of BPC-157.[6] Thus, allowing these peptides to be compounded would expose consumers to unproven products and displace existing safe and effective FDA-approved treatments, creating a real risk of clinical harm.

**Allowing peptides to be compounded removes incentives to go through FDA's rigorous drug approval process.**
The proposed inclusion of these peptides onto the 503A Bulks List opens a loophole that will be exploited by clinics, telehealth companies, and compounding pharmacies. Not only would this unleash upon unsuspecting consumers a set of products previously deemed too dangerous to compound by the FDA, it would also undermine the FDA drug approval process itself.

We should all be able to agree that what patients need are peptide products that have been proved to be safe and effective. But moving these products, which FDA's own staff have concluded currently lack evidence of safety and effectiveness, to the 503A Bulks List makes it unlikely that such evidence will ever be generated. Companies aspiring to prove the safety and effectiveness of these products will turn away from them, knowing that compounders will simply be able to sell them without ever needing to generate such evidence. The result will be an influx of unproven products with little realistic prospect of ever proving their clinical utility, if they have any. Indeed, financial analysts anticipate a $2.2 billion telehealth market opportunity if the seven peptides are approved for compounding.[8]

**Conclusion**
Secretary Kennedy has argued that adding these substances allows for "regulated access" to keep consumers away from the illegal market.[9] What he means by this is that the people who stand to benefit financially from promoting peptides, some of whom are appointed to this committee, have created so much evidence-free demand, much of it of dubious legality, that FDA now has to succumb to that demand because it is too late to put the genie they have helped create back in the bottle. This Committee has a clear choice: Should it support the decades-old drug approval process that has delivered so many life-saving therapies or should it succumb to pseudoscience and grift, endangering the lives of consumers. For any agency (or committee) priding itself on the protection of public health, that choice should not be a difficult one.

Sincerely,

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**Table 1: FDA Briefing Document Evaluation of the Seven Bulk Drug Substances**

| Bulk Drug Substance Name | Proposed Route of Administration; Uses Evaluated | FDA-Approved Alternative Therapies? | "Historical Use in Compounding" | "Physical and Chemical Characterization" | Safety | Effectiveness |
|---|---|---|---|---|---|---|
| BPC-157 (free base), BPC-157 acetate | Oral, subcutaneous; Ulcerative colitis (UC) | Yes | Currently available data and published literature is too limited for FDA to understand the historical use | Not well characterized from a physical and chemical characterization perspective | Lack of information on the safety profile | Insufficient evidence to make a conclusion on the effectiveness |
| KPV (free base), KPV acetate | Topical; Wound healing and inflammatory conditions | Yes | Extent of KPV (free base) or KPV acetate use in compounding is unknown | Not well characterized from a physical and chemical characterization perspective | Lack of clinical and nonclinical safety information | Lack of evidence to evaluate the effectiveness |
| TB-500 (free base), TB-500 acetate | Intramuscular, subcutaneous; Wound healing | Yes | Currently available data and published literature is too limited for FDA to understand the historical use | Not physically and chemically well-characterized | Lack of clinical and nonclinical safety information | Lack of evidence to evaluate the effectiveness |
| MOTs-C (free base), MOTs-C acetate | Subcutaneous; Obesity and osteoporosis | Yes | Unknown use in compounding | Not well characterized from a physical and chemical characterization perspective | Lack of clinical and nonclinical information | Lack of evidence to evaluate the effectiveness |
| Emideltide (free base), Emideltide acetate | Subcutaneous; Opioid withdrawal, chronic insomnia, and narcolepsy | Yes | These substances have been used historically in compounding* | Not well characterized from a physical and chemical characterization perspective | Insufficient safety information | Lack of evidence of effectiveness |

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| Semax (free base), Semax acetate | Intranasal, subcutaneous; Cerebral ischemia, migraine, and trigeminal neuralgia | Yes | The extent to which semax has been used in compounding is unclear | Not well characterized from a physical and chemical characterization perspective | Lack of information on the safety profile | Insufficient evidence of effectiveness |
| Epitalon (free base), Epitalon acetate | Subcutaneous; Insomnia | Yes | The extent to which any form of epitalon has been used in compounding is unclear | Not well characterized from a physical and chemical characterization perspective | Lack of information to support safety | Lack of evidence to support effectiveness |

*According to the FDA, there is evidence that "emideltide-related BDSs have been used in compounding since at least 2018."[10] However, FDA identified emideltide as a bulk drug substance with "significant safety risks" and added it to the Category 2 list in 2023.[11]

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