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FDA Committee Supports Peptide Compounding: What Comes Next for Compounders, Telehealth Platforms, Med Spas and Others

Key Takeaways

- At its July 23-24 meeting, the FDA's Pharmacy Compounding Advisory Committee voted narrowly in favor of adding six of seven discussed peptides to the FDA's 503A Bulks List, but the vote is advisory and does not automatically change those peptides' legal status.
- Formal revision of the 503A Bulks List requires FDA rulemaking, which can take significant time. In the interim, the FDA could issue new or revised guidance to facilitate compounding with some or all of the peptides discussed.
- Pharmacies, telehealth platforms, med spas, wellness centers and other stakeholders interested in peptide-related opportunities should assess how potential FDA policy changes could affect their business, clinical and operational models.

The Food and Drug Administration's (FDA's) Pharmacy Compounding Advisory Committee (PCAC) met July 23 and 24 to consider seven peptides for inclusion on the agency's 503A Bulks List. PCAC members expressed divergent views but ultimately voted narrowly in favor of adding six peptides — BPC-157, KPV, TB-500, MOTs-C, Semax and Epitalon — to the list. One peptide, Emideltide (DSIP), failed to win PCAC support. While the PCAC vote is only an advisory recommendation, the meeting outcome will increase pressure on the FDA to ease current compounding restrictions for the PCAC-recommended peptides.

This Alert provides an overview of the PCAC meeting outcome, potential FDA next steps and key planning considerations for businesses and providers involved in prescribing, compounding, dispensing, administering or marketing compounded peptide products.

Background and PCAC Meeting Outcome

Drugs compounded by certain state-licensed pharmacies and physicians under section 503A[1] need not obtain FDA approval; bear labeling with adequate directions for use; or be made in compliance with current good manufacturing practice requirements (GMP), so

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long as they meet other statutory conditions. As discussed in our previous Alert, one of those conditions is that a bulk drug substance (bulk) used in compounding must: (i) comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph; (ii) be a component of an FDA-approved drug product; or (iii) appear on the 503A Bulks List established by FDA regulation. For the peptide bulks discussed at the recent PCAC meeting, inclusion on the 503A Bulks List is the currently available statutory pathway to permit their use in compounding.

The FDA must go through formal rulemaking to update the 503A Bulks List, which involves issuing a proposed rule for public comment before that rule is finalized. Therefore, the PCAC meeting did not add any peptide to the list or create an immediate safe harbor for compounding. However, the PCAC vote increases the chance of their future addition to the list and may lead the FDA to issue new or revised policies that would support their use in compounding before the FDA completes any rulemaking on this issue.

What the FDA Could Do Next

The FDA has several potential paths following the PCAC vote, and each would carry different implications for timing, compliance and market planning. Key possibilities include:

Deferring action: The FDA could put off any action on the peptides at issue. In that case, the status quo remains unchanged.

Initiating rulemaking to revise the 503A Bulks List: The FDA may move forward with rulemaking to add some or all discussed peptides to the 503A Bulks List, but this process takes time (often years). Starting that process would not, on its own, resolve current ambiguity around peptide compounding.

Exercising enforcement discretion: The FDA could issue new or revised guidance communicating that it does not intend to take regulatory action against pharmacies that compound using some or all of the peptides brought to the PCAC. Essentially, the FDA would be saying that even if it is technically violative to compound with peptide bulks that are not on the official 503A Bulks List, the agency does not plan to enforce on that basis. Any such policy would likely include conditions that the FDA expects compounders to meet.

The FDA has long taken a similar approach to 503A compounding with “Category 1” bulks.[2] Specifically, the FDA has made clear in guidance that it does not intend to take action against state-licensed pharmacies or licensed physicians that compound from a Category 1 bulk, provided that: (i) the bulk is manufactured solely in FDA-registered establishments; (ii) the bulk is accompanied by a valid certificate of analysis (COA) and (iii) compounding otherwise complies with all requirements under section 503A.

The agency could add some or all discussed peptides to Category 1. It could also potentially create a new policy with additional limits on the scope of enforcement discretion. For example, some PCAC members limited their support for particular peptides to specific routes of administration, and the FDA could seek to limit its enforcement discretion policy to routes that it judges to be lower risk. Stakeholders should therefore review carefully any new or revised guidance FDA may issue on this topic. Important details would include:

- Which peptides are covered?
- Does the policy apply to 503A compounders only, or are 503B outsourcing facilities in scope?
- Are there limits on route of administration, dosage form, patient population, or clinical

use?
- Does the policy describe specific sourcing, testing, documentation, or quality expectations?

Key Planning Considerations for Compounders, Telehealth Platforms, Med Spas and Other Stakeholders

Below, we outline some key considerations that stakeholders should consider as they prepare for potential policy changes regarding the peptides discussed at the PCAC meeting.

It's important to keep in mind that the term "peptide" is used broadly, and different "peptides" may raise different legal considerations. The PCAC also did not resolve questions around marketing peptides as dietary supplements. As reflected in comments submitted in connection with the meeting, some stakeholders have shown interest in pursuing the use of naturally occurring peptides under the regulatory pathways for foods or dietary supplements, which involve different legal considerations and requirements than pathways for drug compounding.

Stakeholders should separately evaluate each "peptide" and the basis for marketing it and seek legal or regulatory guidance if they have questions.

503A Compounding Pharmacies: Pharmacies preparing for peptide compounding should consider:

- Identifying and vetting potential API suppliers to, among other things, gain a full understanding of the supply chain, including the identity, FDA registration status and GMP compliance of all parties involved (original manufacturer, any repackagers, etc.). Other important vetting items include testing performed to determine product quality and assurance of valid COAs.
- Understanding state licensure requirements to compound and dispense the relevant peptide-based products, including valid patient-specific prescriptions and appropriate documentation of medical necessity, where applicable.

Telehealth Platforms: Telehealth platforms exploring a launch of compounded peptide products should consider whether:

- The platform will adequately disclose to its members any continued regulatory ambiguity over the prescribing of peptide products and the potential risks to its members;
- The platform permits its providers to continue to exercise independent clinical decision-making;
- Provider licensure, pharmacy relationships, patient choice and refill practices are properly structured in accordance with applicable state licensing and permitting requirements; and
- Patient data flows, tracking technologies, SMS/email marketing and vendor arrangements are compliant.

Med Spas, Wellness Centers and Other Providers: Providers interested in offering compounded peptides should assess:

- Sourcing for compounded peptide products and ingredients to promote product quality and safety;
- Who would prescribe, prepare, store, handle and administer the products;
- Clinical criteria for participation in any peptide program;

- Public and patient-facing communications regarding peptide offerings and programs, including compliance with state laws governing physician/practitioner advertising;
- Applicable medical director, supervision, delegation and scope-of-practice requirements, including any state-specific practice guidance specifically related to these issues; and the
- Appropriateness and completeness of patient consents and disclosures.

General Advertising Considerations: All stakeholders should plan to implement a review process for any website, paid influencer content, social media and other marketing materials before they go live, particularly given recent regulatory scrutiny of direct-to-consumer advertising of compounded GLP-1 products and state-level enforcement (such as in California) of provider communications with patients.

Stakeholders can take steps now to be ready to respond quickly to any future changes in FDA peptide compounding policy. While we believe the PCAC meeting increases the likelihood of policy changes, those changes are not guaranteed, and new policies could come with limitations. State pharmacy and/or professional boards and other state regulators are not required to align with FDA guidance, so it will be important to monitor relevant state-level developments as well.

For questions about the PCAC meeting, FDA and state pharmacy board requirements, telehealth prescribing, provider considerations or advertising and promotional materials, please contact Mark Armstrong, Claire Davies, Stuart Pape, Paul Squire, Ryan Thurber or your regular Polsinelli attorney.

[1] Section 503A of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 353a.

[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/interim-policy-compounding-using-bulk-drug-substances-under-section-503a-federal-food-drug-and