

FDA Advisory Committee Recommends Several Peptides for Compounding for Various Uses Despite Staff Opposition- What Stakeholders Need to Know

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What happens when an FDA advisory committee recommends opening the door to peptide compounding, but FDA staff strongly disagree? In this episode, we unpack the FDA Pharmacy Compounding Advisory Committee's recommendation to add six of seven peptides under review to the 503A Bulks List for uses ranging from obesity and wound healing to insomnia, despite agency staff raising concerns about insufficient safety and effectiveness data, limited clinical evidence, and potential safety risks. We also explore why the recommendations are not a green light for compounding or marketing these substances: FDA must still complete a formal rulemaking process, and the agency is not required to follow the Committee's advice. For compounding pharmacies, wellness providers, telehealth platforms, manufacturers, and investors, the key takeaway is clear: enforcement risk remains, and caution is still warranted.

Hosted by Simone Roach. Based on a blog post by [Donnelly L. McDowell](#) and [Cristina Ferretti](#).