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Peptides Take Center Stage at FDA's Critical Stakeholder Meeting

Key Takeaways

- The FDA's Pharmacy Compounding Advisory Committee meeting later this month will evaluate whether seven peptides should be eligible for compounding under Section 503A. Strong support from PCAC may signal future change in the FDA's policies regarding the compounding of some or all of these peptides.
- Stakeholders can still submit comments through July 22.

As discussed in our previous alert, the U.S. Food and Drug Administration's (FDA) much-anticipated Pharmacy Compounding Advisory Committee (PCAC) meeting is scheduled for July 23–24. The PCAC will discuss whether seven peptides should be included on the list of bulk drug substances that may be used in compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act. Although the July 9 deadline for submitting comments for distribution to committee members has passed, the FDA's public docket remains open through July 22. Comments submitted after July 9 but on or before July 22 will still be considered by the FDA.

The PCAC is advisory and does not have the authority to decide whether a substance will be added to the 503A Bulks List. However, strong support from the committee may signal a future change in the FDA's policies regarding the compounding of some or all of the peptides scheduled for discussion. We will closely monitor the PCAC meeting and provide an update on post-meeting developments.

Should you have questions regarding the legal and regulatory considerations associated with a particular peptide or peptide compounding — either before or after the PCAC meeting — please contact the authors of this alert or your preferred Polsinelli attorney.

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