

FDA rules for compounded peptides, in plain words

How sections 503A and 503B decide which peptides a pharmacy may compound, what the February 2026 Category 1 news changed, and where to check the current status.

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This guide explains the rules that decide which peptides a compounding pharmacy in the United States may use. It is a directory's explainer, not legal or medical advice, and it was last checked on 2026-10-20. Rules in this area are changing, so always confirm on the FDA pages linked below.

The two kinds of compounder

US law splits drug compounding into two tracks:

- **503A pharmacies.** State-licensed pharmacies that compound a drug for an individual patient, against a prescription. A 503A pharmacy may use a bulk substance only when it has a USP or NF monograph, is a component of an FDA-approved drug, or appears on the FDA's 503A bulks list.
- **503B outsourcing facilities.** Facilities that register with the FDA and may compound larger batches without patient-specific prescriptions, under federal quality standards. The FDA publishes the list of registered outsourcing facilities, and it is public.

The bulks lists

Sections 503A and 503B each have a list of bulk drug substances that may be used in compounding. The FDA is still developing both lists and groups nominated substances into categories: Category 1 (under evaluation), Category 2 (raises significant safety risks) and Category 3 (nominated without adequate support). Several peptides that clinics have commonly prescribed sit in these nomination categories.

The February 2026 change

In February 2026, an HHS announcement said about 14 peptides would move back to the FDA Category 1 list — the category of substances still under evaluation, which the agency's interim policy has generally allowed compounders to use while the evaluation runs. Sources disagree on the final status and on what the announcement changes in practice. Treat any single article, including the interpretation of a clinic's marketing page, with care and check the primary source.

Where to check

- FDA page on bulk drug substances used in compounding: <https://www.fda.gov/drugs/human-drug-compounding/bulk-drug-substances-used-compounding>

- FDA list of registered 503B outsourcing facilities: <https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities>
- The 503A and 503B bulks-list pages, linked from the first page above.

What this means for a listing on this site

A 503B registration is a federal facility registration, not a licence to prescribe. A clinic's licence comes from a state board; a pharmacy's licence comes from a state board of pharmacy. This directory records, for each listing, where its licence claim was checked and when. A listing is a record, not an endorsement, and nothing here is dosing guidance or medical advice.

Frequently asked questions

What is the difference between 503A and 503B?

A 503A pharmacy is state-licensed and compounds for individual prescriptions. A 503B outsourcing facility registers with the FDA and can compound larger batches under federal quality standards. Different bulk-substance rules apply to each.

Are compounded peptides FDA-approved?

No. Compounded preparations are not FDA-approved drugs. Whether a bulk substance may be compounded at all depends on the FDA bulks lists and the rules for the facility type, which are changing.

Where do I check the current status?

The FDA bulk-substances page and the 503A and 503B bulks-list pages on fda.gov. They are the primary source; this guide points at them rather than repeating a status that can go stale.