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**New Proposed FDA Compounding Rule**

With everything we have been discussing lately on compounding, the FDA has just released a new proposed rule seen [here](https://www.federalregister.gov/documents/2024/03/20/2024-05801/drug-products-or-categories-of-drug-products-that-present-demonstrable-difficulties-for-compounding).

The proposal would create new lists of drugs that cannot be legally compounded and allow a process in which stakeholders can submit products they believe should be on the lists for agency consideration. The proposal seeks to establish criteria for the lists of drug products or categories of drug products that appear on the “Demonstrable Difficulties for Compounding” (DDC) lists of drugs that do not quality for certain statutory exemptions under the Food, Drug & Cosmetic (FD&C) Act and therefore cannot be compounded at pharmacies. A comment period will be open for 90 days.

**The proposal would also initially add three categories of drug to the lists:**oral solid modified-release drug products that employ coated systems, liposome drug products and drug products produced using hot melt extrusion.

The rule would create two lists based on different sections of the FD&C Act. Section 503A concerns drugs that can be compounded by a licensed pharmacist in a state-licensed pharmacy or federal facility, or by a licensed physician, and creates exemptions from some regulations on current good manufacturing, labeling and drug approvals. Section 503B concerns drugs compounded in an outsourcing facility under supervision of a pharmacist and creates exemptions from regulations on approvals, labeling and drug supply chain security requirements.