

Updated March 1, 2019

### 503B Bulks List

Outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act may use a [bulk drug substance](#) to compound a drug if:

- the FDA has determined there is clinical need to compound with the substance and places it on a list of such drugs (the 503B bulks list), or
- the drug compounded appears on the FDA's drug shortage list at the time of compounding, distribution, and dispensing.

The agency is evaluating bulk drug substances that were nominated for inclusion on the 503B bulks list, proceeding case by case, under the standard provided by the statute.

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At this time, FDA has not placed any bulk drug substances on the 503B bulks list.

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FDA has evaluated the following bulk drug substances and decided not to include them on the list of substances that can be used in compounding under section 503B of the FD&C Act:

- Nicardipine Hydrochloride
- Vasopressin