Updated January 27, 2022

503B Bulks List

To qualify for exemptions under section 503B of the Federal Food, Drug, and Cosmetic Act, a compounded drug must meet a number of conditions in section 503B. Among the conditions is that the drug must be compounded in an outsourcing facility that does not compound using bulk drug substances unless:

- 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 from the bulk drug substance appears on the FDA's drug shortage list at the time of compounding, distribution, and dispensing.

FDA 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.

FDA has evaluated the following bulk drug substances and determined that there is a clinical need for outsourcing facilities to compound drug products using these bulk drug substances under section 503B of the FD&C Act:

Bulk Drug Substances Included on the 503B Bulks List	FR Citation	Date of FRN Publication
Diphenylcyclopropenone (for topical use only)	87 FR 4240	01/27/2022
Glycolic acid (for topical use in concentrations up to 70% only)	87 FR 4240	01/27/2022
Squaric acid dibutyl ester (for topical use only)	87 FR 4240	01/27/2022
Trichloroacetic acid (for topical use only)	87 FR 4240	01/27/2022

FDA has evaluated the following bulk drug substances and determined that there is **not** a clinical need for outsourcing facilities to compound drug products using these bulk drug substances under section 503B of the FD&C Act:

Bulk Drug Substances Not Included on the 503B Bulks List	FR Citation	Date of FRN Publication
Diazepam	87 FR 4240	01/27/2022
Dipyridamole	87 FR 4240	01/27/2022
Dobutamine hydrochloride	87 FR 4240	01/27/2022
Dopamine hydrochloride	87 FR 4240	01/27/2022
Edetate calcium disodium	87 FR 4240	01/27/2022
Folic acid	87 FR 4240	01/27/2022
Glycopyrrolate	87 FR 4240	01/27/2022
Nicardipine hydrochloride	84 FR 7383	03/04/2019
Sodium thiosulfate (except for topical administration)[1]	87 FR 4240	01/27/2022
Vasopressin	84 FR 7383	03/04/2019

[1] As described in the *Federal Register* of January 27, 2022 (87 FR 4240), FDA intends to evaluate sodium thiosulfate for topical use only in a future *Federal Register* notice.