Updated August 21, 2023

503B Bulks List

Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) describes the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from certain provisions of the FD&C Act. Among the conditions is that the drug must be compounded in an outsourcing facility that does not compound using bulk drug substances (active pharmaceutical ingredients, or APIs) unless:

- the FDA has determined there is clinical need to compound with the substance and places it on 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
Quinacrine HCl (for oral use only)	88 FR 20531	04/06/2023
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
Ephedrine sulfate	88 FR 56837	08/21/2023
Folic acid	87 FR 4240	01/27/2022
Glycopyrrolate	87 FR 4240	01/27/2022
Hydroxychloroquine sulfate	88 FR 56837	08/21/2023
Hydroxyzine hydrochloride	88 FR 20531	04/06/2023
Mannitol	88 FR 20531	04/06/2023
Methacholine chloride	88 FR 20531	04/06/2023
Metoclopramide hydrochloride	88 FR 20531	04/06/2023
Nalbuphine hydrochloride	88 FR 20531	04/06/2023
Nicardipine hydrochloride	84 FR 7383	03/04/2019
Potassium acetate	88 FR 20531	04/06/2023
Procainamide hydrochloride	88 FR 20531	04/06/2023
Sodium bicarbonate	88 FR 20531	04/06/2023
Sodium nitroprusside	88 FR 20531	04/06/2023
Sodium thiosulfate (except for topical administration)[1]	87 FR 4240	01/27/2022
Vasopressin	84 FR 7383	03/04/2019
Verapamil hydrochloride	88 FR 20531	04/06/2023

[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.