



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3240]

List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for a notice that appeared in the *Federal Register* of July 31, 2020, in which FDA identified certain bulk drug substances (active pharmaceutical ingredients) that FDA has considered and proposes to include or not include on the list of bulk drug substances for which there is a clinical need (the 503B Bulks List). The Agency is taking this action in response to a request received during the initial comment period, which asked the Agency to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the notice published on July 31, 2020 (85 FR 46126). Submit either electronic or written comments by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-3240 for "List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Received comments, those filed in a timely manner

(see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Dominic Markwordt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5104, Silver Spring, MD 20993, 301-796-9349.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of July 31, 2020 (85 FR 46126), FDA published a notice that identified four bulk drug substances that FDA considered and proposed to include on the 503B Bulks List: diphenylcyclopropanone (DPCP), glycolic acid, squaric acid dibutyl ester (SADBE), and trichloroacetic acid (TCA). The July 31, 2020, notice also identified 19 bulk drug substances that FDA considered and proposed not to include on the 503B Bulks List: diazepam, dobutamine hydrochloride (HCl), dopamine HCl, edetate calcium disodium, folic acid, glycopyrrolate, hydroxyzine HCl, ketorolac tromethamine, labetalol HCl, mannitol, metoclopramide HCl, moxifloxacin HCl, nalbuphine HCl, polidocanol, potassium acetate, procainamide HCl, sodium nitroprusside, sodium thiosulfate, and verapamil HCl. Interested persons were originally given until September 29, 2020, to comment on FDA's proposals.

During the comment period for the July 31, 2020, notice, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period of 60 days was insufficient to respond fully to FDA's specific requests for comments and noted the commenter's obligations to respond to the exigencies of COVID-19 pandemic.

FDA has considered the request and other relevant factors, and accordingly is reopening the comment period for the July 31, 2020, notice for 30 days, until **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The Agency believes that an additional 30 days will allow adequate time for interested persons to submit comments.

Dated: January 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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