



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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice entitled “List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act” that appeared in the *Federal Register* of May 1, 2026. In the *Federal Register* notice, FDA requested comments on FDA’s proposal not to include semaglutide, tirzepatide, or liraglutide on a list of bulk drug substances (active pharmaceutical ingredients) for which there is a clinical need for outsourcing facilities to use in compounding (the 503B Bulks List). The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published in the *Federal Register* of May 1, 2026 (91 FR 23431). Either electronic or written comments must be submitted by July 30, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 30, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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: Tracy Rupp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-0260, compounding@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 1, 2026, FDA published a notice with a 60-day comment period to request comments on FDA's proposal not to include semaglutide, tirzepatide, or liraglutide on the 503B Bulks List. Comments on the proposal will inform FDA's final determination whether to include these substances on the 503B Bulks List.

The Agency has received a request for a 60-day extension of the comment period for the May 1, 2026 *Federal Register* notice. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the *Federal Register* notice. The request states that the additional time will allow interested parties to develop rigorous and comprehensive comments that will address complex clinical, public health, and legal issues; engage thoughtfully with a complicated regulatory landscape; and thoroughly address issues around patient safety and access to high-quality medications.

FDA has considered the request and is extending the comment period for the *Federal Register* notice for 30 days, until July 30, 2026. The Agency believes that a 30-day extension, rather than 60 days, appropriately balances allowing adequate time for interested persons to submit comments with avoiding significant delay of Agency action on these important issues. FDA encourages comments to address the clinical need standard provided by the statute and FDA's rationale in the May 1, 2026 *Federal Register* notice.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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