Collaborative for Evidence-Based Medicines:
Putting Patient Safety First
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June 4, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: 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"

The Collaborative for Evidence-Based Medicines ("CEBM") is a national provider-led organization advancing evidence-backed medicines, safe compounding, and stronger oversight and accountability to protect patients. CEBM brings together providers, patient advocates, academics, consumer groups, manufacturers, and other stakeholders to advance our patient safety mission.

CEMB writes to respectfully request at least a 60-day extension to the comment period for 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* (the "Notice").

On May 1, 2026, the Food and Drug Administration ("FDA") issued the Notice identifying semaglutide, tirzepatide, and liraglutide as bulk drug substances that FDA has considered and proposed not to include on the 503B Bulks List, with comments due by June 30, 2026. FDA's preliminary determination reflects a thorough evaluation of these bulk drug substances and whether there is a clinical need for outsourcing facilities to compound these bulk drug substances. However, given the significance of this decision, a 60-day comment period is insufficient for stakeholders to provide the robust evidence-based comments needed to build a strong and durable record.

The complex clinical, public health, and legal issues implicated in FDA's decision warrant additional time for stakeholders to develop rigorous and comprehensive comments. The Notice applies a multi-factor evaluation framework across three bulk drug substances with distinct nominations and docket comment histories, each of which raises complex scientific questions. This is a complicated regulatory landscape that warrants giving stakeholders additional time to engage thoughtfully. Indeed, FDA has previously granted at least one extension request to allow for more time to submit comments on 503B Bulks List nominations, and regularly grants such requests for other issues involving complex scientific and regulatory considerations.[1]

[1] *See* 86 Reg. 1515 (Jan. 8, 2021) ("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").

The need to thoroughly address issues around patient safety and access to high-quality medications is the central reason for this request. The stakes are high for patients, and stakeholders need more time to address these multifaceted issues.

For these reasons, we respectfully ask FDA to extend the comment period by at least 60 days. Additional time will only strengthen the agency's ultimate determination by ensuring it is backed by a more comprehensive record.

We thank the FDA for considering our request to extend the comment period. For questions regarding this request, please contact John Hertig, Chair of the Collaborative for Evidence-Based Medicines (317-600-6029; jhertig@hertighealthcareadvising.com).

Sincerely,

John Hertig, PharmD, MS, CPPS, FASHP
Chair, Collaborative for Evidence-Based Medicines

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As recently as May 28, 2026, FDA extended a comment period out of the 503B Bulks List nominations: 91 Fed. Reg. 31725 (May 28, 2026) ("FDA is extending the comment period on the request for information published April 29, 2026 (91 FR 23100). Either electronic or written comments must be submitted by June 29, 2026.")

Additional examples outside of 503B Bulks List nominations include: 91 Fed. Reg.13038 (Mar. 18, 2026) ("We have received a request to extend the comment period for this notice. Pointing to the complexity of the issues and information requested and the need to collect responsive information, the request asserts that additional time would allow stakeholders to provide FDA with more thorough and useful responses. We have considered the request and are extending the comment period for the notice by 30 days, until April 22, 2026. We believe that the extension will allow adequate time for interested persons to submit comments."); U.S. Food and Drug Administration, "HHS, FDA and USDA Extend Comment Period for Data and Information on Ultra-Processed Foods" issued Sept. 18, 2025, *available at*: https://www.fda.gov/food/hfp-constituent-updates/hhs-fda-and-usda-extend-comment-period-data-and-information-ultra-processed-foods ("The original comment period was scheduled to close on September 23, 2025. In response to requests for an extension, we are extending the comment period by 30 days, until October 23, 2025, to allow interested persons additional time to submit comments."); U.S. Food and Drug Administration, "FDA Extends Comment Period for Proposed Method for Ranking Chemicals in Food for Post-market Assessments" issued July 14, 2025, *available at*: https://www.fda.gov/food/hfp-constituent-updates/fda-extends-comment-period-proposed-method-ranking-chemicals-food-post-market-assessments ("The original comment period was scheduled to close on July 18, 2025. In response to requests, FDA is now extending this deadline by 30 days to August 18, 2025, to provide additional time for stakeholders to review the proposed method and submit comprehensive feedback.").

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