

OFA submitted a comment on March 17, 2025 (FDA-2024-P-5966-0003),⁶⁷ responding to arguments made in the citizen petition. Covington & Burling LLP on behalf of NNI submitted a supplement to its earlier comment on June 17, 2025 (FDA-2024-P-5966-0005),⁶⁸ responding to OFA's comments.

IV. Conclusion

For the reasons stated above, FDA tentatively finds no basis to conclude that there is a clinical need for an outsourcing facility to compound using the following bulk drug substances: semaglutide, tirzepatide, and liraglutide. Therefore, we propose not to include these bulk drug substances on the 503B Bulks List.

V. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (**SEE ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

- * 1. FDA Memorandum to File, "Clinical Need Evaluation for Semaglutide in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act," April 2026.
2. Pratap-Singh, A, Y Guo, A Baldelli and A Singh, 2023, Concept for a Unidirectional Release Mucoadhesive Buccal Tablet for Oral Delivery of Antidiabetic Peptide Drugs Such as Insulin, Glucagon-Like Peptide 1 (GLP-1), and their Analogs, *Pharmaceutics*, 15(9):2265.
3. Wilding, JPH, RL Batterham, S Calanna, M Davies, LF Van Gaal, I Lingvay, BM

issues raised in the nominations and comments to the docket, including relevant portions of the petition that was enclosed in NNI's comment. FDA's final decision on those issues will be reflected in the final **Federal Register** notice and response to the petition. FDA intends to issue the response to the petition concurrently with the **Federal Register** notice setting forth FDA's final decision about whether liraglutide will be added to the 503B Bulks List.

⁶⁷ Available at <https://www.regulations.gov/document/FDA-2024-P-5966-0003>.

⁶⁸ Available at <https://www.regulations.gov/document/FDA-2024-P-5966-0005>.

McGowan, J Rosenstock, MTD Tran, TA Wadden, S Wharton, K Yokote, N Zeuthen and RF Kushner for the STEP 1 Study Group, 2021, Once-Weekly Semaglutide in Adults with Overweight or Obesity, *N Engl J Med*, 384(11):989-1022.

4. Blum, D, 2024, The Allure of 'Microdosing' Ozempic, *The New York Times*, available at <https://www.nytimes.com/2024/12/05/well/ozempic-microdose-weight-loss.html>.
5. Aroda, VR, J Aberle, L Bardtrum, E Christiansen, FK Knop, S Gabery, SD Pedersen and JB Buse, 2023, Efficacy and Safety of Once-Daily Oral Semaglutide 25 mg and 50 mg Compared with 14 mg in Adults with Type 2 Diabetes (PIONEER PLUS): A Multicentre, Randomised, Phase 3b Trial, *Lancet*, 402(10403):693-704.
6. Knop, FK, VR Aroda, RD do Vale, T Holst-Hansen, PN Laursen, J Rosenstock, DM Rubino and WT Garvey for the OASIS 1 Investigators, 2023, Oral Semaglutide 50 mg Taken Once per Day in Adults with Overweight or Obesity (OASIS 1): A Randomised, Double-Blind, Placebo-Controlled, Phase 3 Trial, *Lancet*, 402(10403):705-719.
7. Snitker, S, A Andersen, PS Lindskov, S van Marle, BF Sode and T Sparre, 2022, Comparison of the Injection-Site Experience of Semaglutide in a Single-Dose and a Multidose Pen-Injector, *Diabetes Obes Metab*, 24(8):1643-1646.
- * 8. FDA Memorandum to File, "Clinical Need Evaluation for Tirzepatide in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act," April 2026.
- * 9. FDA Memorandum to File, "Clinical Need Evaluation for Liraglutide in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act," April 2026.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Office of AIDS Research Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting. The meeting

can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

Name of Committee: Office of AIDS Research Advisory Council.

Date: June 25, 2026.

Time: 12:00 p.m. to 04:30 p.m.

Agenda: The 72nd Office of AIDS Research Advisory Council meeting will include a report from the Office of AIDS Research Director, and discussions with council members, guests, and NIH officials regarding NIH HIV research.

Address: Office of AIDS Research, Office of the Director, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Melissa Herrera, Office of AIDS Research, Office of the Director, National Institutes of Health, 5601 Fishers Lane, Room 2F18, Rockville, MD 20892, (301) 496-0357, OARACinfo@nih.gov.

Registration is not required to attend this meeting.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: April 28, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

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