U.S. FOOD & DRUG ADMINISTRATION

Julie Dohm
Covington & Burling LLP
850 Tenth Street, NW
Washington, DC 20001-4956

June 18, 2025

Re: Docket No. FDA-2024-P-5966

Dear Dr. Dohm:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on December 21, 2024, and submitted on behalf of Novo Nordisk Inc. Your petition requests that the Agency:

1) Publish a notice in the Federal Register excluding liraglutide from the 503B Bulks List;

2) Rescind in its entirety the Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act ("503B Interim Policy"); and

3) Exclude liraglutide from Category 1 of the 503B Interim Policy.[1]

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S
Digitally signed by Carol Bennett -S
Date: 2025.06.18 10:45:45 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

[1] Petition at 1.

U.S. Food & Drug Administration
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