



October 24, 2024

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: FDA-2024-P-4937, Citizen Petition from Covington & Burling LLP on Behalf of Novo Nordisk Inc.—Outsourcing Facilities Association Comment

To Whom It May Concern:

The Outsourcing Facilities Association (“OFA”), submits this comment in response to the Citizen Petition from Covington & Burling LLP on Behalf of Novo Nordisk Inc. (“Novo”), dated October 21, 2024. The Commissioner and the public has an interest to know the effects on cost and price that Novo’s requested action would have on consumers.

I. The Commissioner should request an Economic Impact statement from Novo

Under 21 CFR 10.30(b)(3):

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

Lawmakers have scrutinized the price of GLP-1 medications, bringing Novo Nordisk’s CEO in front of a Senate hearing.¹ Commissioner Califf has also expressed an interest in the outrageous price for Novo’s drug for which Novo cannot meet demand: “[t]hey should be ashamed of themselves for what they’re charging Americans,” he said on stage at the HLTH conference on the same day that Novo submitted this Citizen Petition. In fact, Commissioner Califf went on to say “[i]t’s not right.”² Accordingly, the Commissioner should request an Economic Impact Statement to assess the cost and price increases based on Novo’s requested action and should

¹ Senate Health, Education, Labor, and Pensions, Hearings to examine Novo Nordisk's high prices for Ozempic and Wegovy for patients with diabetes and obesity, 118th Congress (September 24, 2024).

² Nicole Wetsman, Endoints News, 'It's not right.' Califf slams pharma over weight loss drug prices (Oct. 22, 2024). <https://endpts.com/hlth24-its-not-right-califf-slams-pharma-over-weight-loss-drug-prices/>

regard Novo's petition as incomplete unless and until a version in accordance with the format required by 21 CFR 10.30(b)(3),³ including an economic impact statement, is submitted.

Respectfully submitted,

Lee H. Rosebush



³ Novo violates 21 CFR § 10.30(b)(3) because it does not contain the “full ... factual and legal grounds on which the petitioner relies, including all relevant information ..., as well as representative information known to the petitioner which is *unfavorable* to the petitioner’s position.” (*Emphasis added*)