U.S. FOOD & DRUG ADMINISTRATION

Charles Ludlam
(b) (6)

Sent via email to: (b) (6)

September 4, 2024

Re: Docket No. FDA-2024-P-1223

Dear Mr. Ludlam:

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 March 11, 2024. Your petition requests that the Agency should enhance the warnings and information on labels for Mounjaro/Zepbound, Ozempic/Wegovy, and similar products. Specifically, the petition requests that FDA should (1) require that additional clinical trials be conducted with regard to the loss of lean muscle mass, setting the ideal goal weight for patients, and maintenance of the weight loss and (2) modify and supplement the labels for these products with regard to these issues.

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: 2024.09.03 15:48:58 -04'00'

Carol J. Bennett
Acting Director
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Center for Drug Evaluation and Research

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