U.S. FOOD & DRUG ADMINISTRATION

Patricia A. Zarzycki
[redacted]

March 3, 2023

Re: Docket No. FDA-2022-P-2163

Dear Ms. Zarzycki:

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 September 7, 2022 (Petition). Your petition requests that FDA "amend labeling regulations to require label updates for generic drugs once the reference drug's patents and exclusivities expire and new information is available" (Petition at 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: 2023.03.02 11:13:11 -05'00'

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

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