U.S. FOOD & DRUG ADMINISTRATION

Lisa Myslinski, PharmD
(b) (6)
[redacted]

Re: Docket No. FDA-2019-P-4003

FEB 21 2020

Dear Ms. Myslinski:

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 August 26, 2019. Your petition requests that the Agency "amend the tentative final monograph of Acetaminophen and Caffeine . . . to include the final monograph of meclizine 336.10(d) which would include 6.25mg of Meclizine" (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 J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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