U.S. FOOD & DRUG ADMINISTRATION

Darshan Kulkarni, Esq.
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Re: Docket No. FDA-2019-P-0537

JUL 31 2019

Dear Mr. Kulkarni:

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 February 2, 2019 (Petition). In the Petition, you request that the FDA "consistently ensure that the requirements to manufacture Methscopolamine Bromide USP are adhered to by all Active Pharmaceutical Ingredient (API) and finished product manufacturers of Methscopolamine Bromide tablets" (Petition at 1). Specifically, you express concern that not all manufacturers of methscopolamine bromide are "compliant with" the standards outlined in FDA's guidance for industry *Botanical Drug Development* (December 2016).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

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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