DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 4, 2019

Darshan Kulkarni
The Kulkarni Law Firm
2929 Arch Street, Suite 1700
Philadelphia, PA 19104

Dear Petitioner:

Your petition to the Food and Drug Administration requesting to 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 was received by this office on 02/02/2019.

It was assigned docket number FDA-2019-P-0537. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2019.02.04 15:01:51 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)