



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

August 26, 2019

Lisa Myslinski, PharmD

(b) (6)

Sent via email to: (b) (6)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to amend the tentative final monograph of Acetaminophen and Caffeine FR Citation 58 FR 28281 to include the final monograph of meclizine 336.10(d) which would include 6.25mg of Meclizine was received by this office on 08/26/2019.

It was assigned docket number FDA-2019-P-4003. 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 Bigby
Supervisory Administrative Proceedings Specialist
Dockets Management Staff
FDA/Office of Operations (OO)