June 6, 2022

B.V. Jagannadha Rao
Medley Pharmaceuticals Ltd.
Medley House, D2, M.I.D.C. Area
Andheri (East), Mumbai-400 093, INDIA

Sent via email to: mail@medleylab.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine whether Chantix (Varenicline Tartrate) Tablets 0.5 mg and 1 mg, approved under New Drug Application ("NOA") number 021928, held by PF PRISM CV, has not been withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 & 10.35 by this office on 06/06/2022.

It was assigned docket number FDA-2022-P-1013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.06.06 10:04:47 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)