U.S. FOOD & DRUG ADMINISTRATION

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

November 30, 2022

Re: Docket No. FDA-2022-P-1013

Dear Petitioner:

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 June 6, 2022. Your petition requests that the Agency "determine whether Chantix (Varenicline Tartrate) Tablets 0.5 mg and 1 mg, approved under New Drug Application ("NDA") number 021928, held by PF PRISM CV, has not been withdrawn for reasons of safety or effectiveness."

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 Bennett -S

Digitally signed by Carol Bennett -S
Date: 2022.11.30 09:59:26 -05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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