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

February 27, 2023

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

Dear Petitioner:

This letter responds to your citizen petition submitted to the Food and Drug Administration (FDA or Agency) and received on June 6, 2022 (Petition). In the Petition, you request that FDA determine "whether Chantix (Varenicline Tartrate) Tablets 0.5 [milligram (mg)] and 1 mg, approved under New Drug Application [NDA] number 021928, held by PF PRISM CV, has not been withdrawn for reasons of safety or effectiveness."[1]

The Agency has reviewed its records and determined that Chantix (varenicline tartrate) tablets, 0.5 mg and 1 mg, has not been withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Chantix (varenicline tartrate) tablets, 0.5 mg and 1 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-8767.

Sincerely,

David Faranda -S

Digitally signed by David Faranda -S
Date: 2023.02.27 08:21:05 -05'00'

David Faranda
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

[1] Petition at 1.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov