MEDLEY HOUSE, D-2, M I D C AREA, 16th ROAD, ANDHERI (E),
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E-mail : mail@medleylab.com • CIN-U24230MH1975PLC018296

medley
pharmaceuticals ltd.

Date: June 6, 2022

**VIA ELECTRONIC SUBMISSION**

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061, l-IFA-305
5630 Fishers Lane
Rockville, MD 20852

**CITIZEN PETITION**

Dear Sir or Madam,

Medley Pharmaceuticals Ltd. submits this Petition in accordance with 21 CFR § 10.25 (a) and 10.30, and pursuant to Sections 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and 21 CFR § 314.122 and 314.161 to request that the Food and Drug Administration ("FDA") determine whether a specific listed drug product has not been withdrawn for safety or effectiveness reasons as outlined below.

**A. Action Requested:**

Specifically, Medley Pharmaceuticals Ltd. hereby requests that the FDA 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Tablets 0.5 mg and 1 mg, approved under New Drug Application ("NDA") number 021928, held by PF PRISM CV, has not been withdrawn for reasons of safety or effectiveness.

**B. Statement of Grounds:**

Under the FDC Act § 505(j), an Abbreviated New Drug Application ("ANDA") must rely on FDA's approval of a Reference Listed Drug ("RLD"). If the RLD was withdrawn from the marketing by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness. If FDA determines that the RLD was withdrawn from sale for reasons of safety and effectiveness, then the drug listing is removed from the Orange Book. If FDA determines that the RLD was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as Basis of Submission.

Chantix (Varenicline Tartrate) Tablets 0.5 mg and 1 mg, approved under NDA 021928, appears in the "Discontinued Drug Products" section of the Orange Book. Generally, approved products are added to the Discontinued Drug Product List when an applicant notifies the Orange Book staff that the product is no longer being marketed. The Discontinued Drug Product List contains

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products for which the FDA has determined that they were not withdrawn for safety or effectiveness reasons, along with products for which FDA has not yet made such a determination. Chantix (Varenicline Tartrate) Tablets 0.5 mg and 1 mg, approved under NDA 021928, appears on the Discontinued Drug Products List but there is no notation as to whether it was withdrawn for safety or effectiveness reasons.

Petitioner respectfully requests that the FDA determine that Chantix (Varenicline Tartrate) Tablets 0.5 mg and 1 mg, approved under NDA 021928, was not withdrawn for safety or effectiveness reasons. The appropriate page from the electronic edition of the Orange Book is enclosed for your reference.

**C. Environmental Impact:**

Medley Pharmaceuticals Ltd., claims a categorical exclusion under 21 CFR § 25.31.

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25 .31.

**D. Economic Impact Statement:**

Medley Pharmaceuticals Ltd., does not believe that this requirement is applicable at this time, but will agree to submit economic impact information, in accordance with 21 CFR § 10.30(b), if requested by the Agency.

**E. Certification:**

Medley Pharmaceuticals Ltd., certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

**Enclosures:**

**Attachment 1**: Approved Drug Products with Therapeutic Equivalence Evaluations, accessed June 5, 2022 (Orange Book)

Sincerely,
For Medley Pharmaceuticals Ltd.

06/06/2022

MEDLEY PHARMACEUTICALS LIMITED MUMBAI 400093

**B. V. Jagannadha Rao.**
VP – R&D, Medley Pharmaceutical's Ltd.,
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