UNICHEM
PHARMACEUTICALS (USA), INC.

ELECTRONIC SUBMISSION VIA REGULATIONS.GOV

Date: February 13, 2020 **Ref #** CP/UNI/2020/001

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned Unichem Pharmaceuticals (USA), Inc., the US Agent submits this Citizen petition on behalf of Unichem Laboratories Limited ("UNICHEM"), pursuant to Federal Food, Drug, and Cosmetic Act ("FD&C Act") and in accordance with regulations at 21 C.F.R. §10.25(a), § 10.30, and 21 C.F.R. § 314.161, requesting the Commissioner of Food and Drug Administration to provide a determination on whether a listed drug has been voluntarily withdrawn for safety or effectiveness reason as outlined below:

A. Action Requested

The petitioner requests the Commissioner of the Food and Drug Administration to determine whether the Reference Listed Drug (RLD), TENEX® (Guanfacine Hydrochloride) Tablets, 1 mg and 2 mg, NDA 019032 held by PROMIUS PHARMA LLC ("PROMIUS"), has been voluntarily withdrawn from the market or withdrawn from sale for safety or effectiveness reason.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products in the Orange Book. The list, 'Approved Drug Products with Therapeutic Equivalence Evaluations', referred to as the "Orange Book", lists all FDA approved drug products. These drug products are generally eligible for submission under Section 505(j) of the FD&C Act as ANDAs.

TENEX® (Guanfacine Hydrochloride) Tablets, NDA 019032 held by PROMIUS, was first approved on Oct 27, 1986 for 1 mg strength and later 2 mg strength was approved on

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Nov 7, 1988. The product was then considered to be a "listed drug product" in the Orange Book. TENEX® (Guanfacine Hydrochloride) Tablets, NDA 019032 now appears in the "Discontinued Section" of the Orange Book (refer to Exhibit-1), indicating that it is currently not available for sale. If RLD appears in the Discontinued Section of the Orange Book and the FDA has not determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, an applicant must submit a citizen petition under 21 C.F.R. § 10.25(a) and § 10.30, seeking a determination on whether the listed drug has been withdrawn from sale for safety or effectiveness reasons. Such a petition must contain all evidence available to the petitioner concerning the reason that the drug product was withdrawn from sale under 21 C.F.R. § 314.122(a). If the FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness, then the drug listing is removed from the Orange Book. See 21 C.F.R. § 314.122, § 314.161, and § 314.162.

The Orange Book lists the TENEX® (Guanfacine Hydrochloride) Tablets, NDA 019032 held by PROMIUS as RLD with the market-status as discontinued in the Orange Book. Currently, the Orange book lists ANDA 074796 of MYLAN PHRAMCEUTICALS INC. as the Reference Standard (RS) for Guanfacine Hydrochloride Tablets, 2 mg.

Petitioner is further unaware of any reason why TENEX®, NDA 019032 may have been removed from sale while other ANDAs for generic TENEX® are still in the market. Therefore, the petitioner believes that the discontinuation of TENEX®, NDA 019032 was due to commercial considerations. Petitioner requests FDA to confirm that the NDA Holder for TENEX®, NDA 019032 has not withdrawn the product for reason of safety or effectiveness.

C. Environmental Impact

In accordance with the requirements set forth in 21 C.F.R. § 25.31(a), the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

D. Economic Impact Statement

The petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

E. Certification

The undersigned 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 unfavourable to the petition.

Sincerely,

Kartik M. Keertikar

Manager, Regulatory Affairs

Unichem Pharmaceutical (USA), Inc.

U.S. Agent

Exhibit-1:
Screenshot of the electric Orange Book search results for TENEX® Tablets (NDA 019032; Promius Pharma LLC) showing Marketing Status as **discontinued**.