DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 14, 2020

Kartik M. Keertikar
Manager, Regulatory Affairs
Unichem Pharmaceuticals (USA), Inc.
One Tower Center Blvd.
Suite 2200
East Brunswick, NJ 08816

Sent via email to: regaffairs@unichemusa.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to determine whether the Reference Listed Drug (RLD), TENEX® (Guanfacine Hydrochloride) Tablets, l mg and 2 mg, NOA 019032 held by PROMIUS PHARMA LLC ("PROMIUS"), has been voluntarily withdrawn from the market or withdrawn from sale for safety or effectiveness reason was received by this office on 02/13/2020.

It was assigned docket number FDA-2020-P-0813. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2020.02.14 15:58:54 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)