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

Re: Docket No. FDA-2020-P-0813

Dear Mr. Keertikar: June 24, 2020

This letter responds to your citizen petition received on February 13, 2020, requesting that the Food and Drug Administration (FDA) determine whether TENEX (guanfacine hydrochloride) tablets, 1 milligram (mg) and 2 mg, approved under new drug application 019032 held by Promius Pharma LLC, was voluntarily withdrawn from the market or withdrawn from sale for safety or effectiveness. FDA has also, on our own initiative, included a determination for TENEX (guanfacine hydrochloride) tablets, 3 mg.

FDA has reviewed its records and determined that TENEX (guanfacine hydrochloride) tablets, 1 mg, 2 mg, and 3 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain TENEX (guanfacine hydrochloride) tablets, 1 mg, 2 mg, and 3 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) 796-9120.

Sincerely,

Jessica G. Tierney -S

Digitally signed by Jessica G. Tierney -S
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Jessica Tierney
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure