

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

KURT R. KARST

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D.C. 20005-5929
(202) 737-5600

FACSIMILE
(202) 737-9329

www.hpm.com

Direct Dial (202) 737-7544
kkarst@hpm.com

December 3, 2020

BY ELECTRONIC SUBMISSION

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

RE: Docket No. FDA-2019-P-3803

Dear Sir or Madam:

Petitioner has become aware of FDA's October 2020 final guidance, "Referencing Approved Drug Products in ANDA Submissions," in which FDA states that applicants may submit controlled correspondence to ask FDA to designate a new reference listed drug or select a reference standard ("RS"). Because the controlled correspondence pathway is now available, Petitioner requests withdrawal of the above-referenced citizen petition requesting that, due to market unavailability of the current RS, FDA designate as a new RS Guanfacine Hydrochloride Tablets, Eq 1mg base and Eq 2mg base, approved under abbreviated new drug application (ANDA) 075109 and held by Amneal Pharmaceuticals Inc. (or another appropriate ANDA). As such, a formal response to Docket No. FDA-2019-P-3803 is no longer necessary.

Sincerely,



Kurt R. Karst