FDA U.S. FOOD & DRUG ADMINISTRATION

Kurt R. Karst, Esq.
Hyman, Phelps & McNamara P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

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

FEB 07 2020

Dear Mr. Karst:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition, received on August 12, 2019. Your petition requests that the Agency designate an additional or new reference standard for Guanfacine Hydrochloride Tablets Eq 1 mg base and Eq 2mg base in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). Your petition specifically recommends the product approved under abbreviated new drug application (ANDA) 075109 held by Amneal Pharmaceuticals as a Reference Standard for purposes of FDA evaluation of ANDAs.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 C.F.R. §10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research