DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 12, 2019

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

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate ANDA 075109 (Guanfacine Hydrochloride Tablets, Eq 1mg base and Eq 2mg base) as a RS for purposes of FDA evaluation of ANDAs for Guanfacine Hydrochloride Tablets, Eq 1mg base and Eq 2mg base was received by this office on 08/12/2019.

It was assigned docket number FDA-2019-P-3803. 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: 2019.08.13 11:40:44 -04'00'

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