DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Silver Spring MD 20993

August 14, 2020

Matthew Weinberg, CEO The Weinberg Group LLC 1129 Twentieth St, NW, Suite 600 Washington, DC 20036

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA declare that the drug products Vasopressin Injection USP, 50 units/2.5 mL (2.5 mL/vial in a single dose vial) and 100 units/5 mL (5 mL/vial in a single dose vial), are suitable for submission as an ANDA was received by this office on 08/14/2020.

It was assigned docket number FDA-2020-P-1766. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

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