DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 20, 2019

Sravani Ravipati, Senior Associate
AuroMedics Pharma LLC
279 Princeton-Hightstown Rd
East Windsor, NJ 08520

Sent via email to: sravipati@aurobindousa.com

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting to permit for submission of ANDA for vasopressin injection 20 units per mL (10 mL fill volume) according to the discontinued formulation of RLD NDA# 204485 Vasostrict ® (vasopressin) Injection, 20 units/mL (1 mL fill) that was deemed acceptable for ANDA submission per agency's response to HPM petition FDA-2017-P-1096 was received by this office on 08/20/2019.

It was assigned docket number FDA-2019-P-3934. 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: 2019.08.21 12:34:26 -04'00'

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

CC: Vincent P. Andolina (vandolina@aurobindousa.com)