DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 4, 2019

Vincent P. Andolina
Vice President, Regulatory Affairs
AuroMedics Pharma LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Sent via email to: vandolina@aurobindousa.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner designate Aurobindo Pharma Ltd.'s Argatroban in Sodium Chloride Injection, 50 mg/50 mL approved under 505(b)(2) NDA 209552 as therapeutically equivalent with an 'AP' rating to the RLD Argatroban in Sodium Chloride Injection, 50 mg/50 mL NDA 022434, held by Eagle Pharmaceuticals, Inc. was received by this office on 06/03/2019.

It was assigned docket number FDA-2019-P-2687. 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: 2019.06.04 10:53:05 -04'00'

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