



October 11, 2022

Vincent P. Andolina, Vice President, Regulatory Affairs
U.S. Agent for Eugia Pharma Specialities Limited
Eugia US, LLC (formerly AuroMedics)
279 Princeton-Hightstown Rd.
East Windsor, NJ 08520-1401

Sent via email to: vandolina@eugiaus.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug designate Eugia'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 212035, held by Accord Healthcare, Inc was received and processed under CFR 10.30 by this office on 10/11/2022.

It was assigned docket number FDA-2022-P-2498. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

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