U.S. FOOD & DRUG ADMINISTRATION

Vincent P. Andolina
Vice President, Regulatory Affairs
Eugia US, LLC
279 Princeton-Hightstown Rd.
East Windsor, NJ, 08520-1401

April 7, 2023

Re: Docket No. FDA-2022-P-2498

Dear Mr. Andolina:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on October 11, 2022. Your petition requests that the Agency assign a therapeutic equivalence code of "AP" to Argatroban in Sodium Chloride Injection, 50 milligrams/50 milliliter, approved under NDA 209552.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Nam E. Kim -S
Digitally signed by Nam E. Kim -S
Date: 2023.04.07 15:53:37 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research