FDA U.S. FOOD & DRUG ADMINISTRATION

Mr. Vincent P. Andolina
AuroMedics Pharma LLC
279 Princeton-Highstown Rd.
East Windsor, NJ 08520

NOV 27 2019

Re: Docket No. FDA-2019-P-2687

Dear Mr. Andolina:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on June 3, 2019. Your petition requests that the Agency assign a TE Code of "AP" to Argatroban in Sodium Chloride Injection, 50 milligrams/50 milliliters, 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,

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov