Michelle R. Ryder
Executive Director
Lachman Consultant Services, Inc.
1600 Stewart Ave, Suite 604
Westbury, NY 11590

September 22, 2022

Re: Docket No. FDA-2022-P-0476

Dear Ms. Ryder:

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 March 29, 2022. Your petition requests that the Agency "determine whether the original formulation submitted for the Reference Listed Drug (RLD), ADRENALIN® (Epinephrine Injection USP, 30 mg/ 30 mL) (1 mg/ mL) (Multiple Dose Vials); New Drug Application (NDA) 204640, held by PAR STERILE PRODUCTS LLC, has been voluntarily withdrawn from the commercial market or withdrawn from sale for reasons of safety or efficacy."

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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 we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2022.09.22 09:48:11 -04'00'

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