U.S. FOOD & DRUG ADMINISTRATION

March 29, 2022

Michelle Ryder
Lachman Consultant Services, Inc.
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Sent via email to: m.ryder@lachmanconsultants.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug 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mL) (Multiple Dose Vials); New Drug Application (NDA) 204640, held by PAR STERILE PRODUCTS LLC, has been voluntarily withdrawn from the commercial market or withdrawn from sale for reasons of safety or efficacy was received and processed under CFR 10.30 by this office on 03/29/2022.

It was assigned docket number FDA-2022-P-0476. 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 Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2022.03.30 14:21:39 -04'00'
Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)