DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug
Administration Rockville,
MD 20857

May 2, 2019

Sharif Ahmed
Principal Consultant
Lachman Consultants
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA determine whether the Reference Listed Drug (RLD), ATROPINE SULFATE ANSYR PLASTIC SYRINGE [Atropine Sulfate Solution; Intravenous, Intramuscular, Subcutaneous, Endotracheal; 0.5mg/5mL (0.1 mg/mL)], New Drug Application (NDA) Number 021146, held by HOSPIRA INC, has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons was received by this office on 05/01/2019.

It was assigned docket number FDA-2019-P-2123. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2019.05.02 13:00:25 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)