DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 18, 2019

Amy Schutte
Senior Associate
Lachman Consultant Services, Inc.
1600 Stewart Av., Suite 604
Westbury, NY 11590

Sent via email: a.schutte@lachmanconsultants.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to designate Nitrofurantoin Oral Suspension 25 mg/5 mL marketed by Nostrum Laboratories Inc. under ANDA 201355, a therapeutic equivalent to the RLD Furadantin® (nitrofurantoin) Oral Suspension 25 mg/5 mL (NDA 009175), as the Reference Standard product was received by this office on 10/18/2019.

It was assigned docket number FDA-2019-P-4879. 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 Bigby
Digitally signed by Dynna Bigby
Date: 2019.10.18 16:34:33 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)