**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration
Rockville, MD 20857

October 27, 2020

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth St, N.W.
Suite 1200
Washington, DC 20005-5929

*Sent via email to:* kkarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate ANDA 201355 (Nitrofurantoin Oral Suspension, 25 mg/5 mL) held by Nostrum Laboratories Inc. as a RS for purposes of FDA evaluation of ANDAs for Nitrofurantoin Oral Suspension, 25 mg/5 mL. Further requests that FDA expedite a response to this petition so that bioequivalence studies can be conducted and an ANDA can be submitted to FDA was received by this office on 10/26/2020.

It was assigned docket number FDA-2020-P-2132. 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: 2020.10.27 11:28:07 -04'00'

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