



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 19, 2020

Muthusamy Shanmugam
Founder and President
Novitium Pharma LLC
70 Lake Drive
East Windsor, NJ 08520

Sent via email to: raoffice@novitiumpharma.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA designate the generic product Mesalamine Enema 4 g/60 mL made by PERRIGO ISRAEL PHARMACEUTICALS LTD (ANDA #076751) as the Reference Standard since Mesalamine Enema 4 g/60 mL of PERRIGO ISRAEL PHARMACEUTICALS LTD is the only one available in the market at present was received by this office on 08/19/2020.

It was assigned docket number FDA-2020-P-1775. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

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