Generic drug manufacturer	:	Novitium Pharma LLC
Generic drug manufacturer's address	:	70 lake drive, East windsor, NJ 08520
Name of the Regulatory Contact	:	Muthusamy Shanmugam
Title		Founder and President
Corporate Email address	:	RAoffice@novitiumpharma.com
Contact phone number	:	845-652-0377

CITIZEN PETITION

Date: August 19, 2020

To,

Division of Dockets Management Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madam,

Novitium Pharma LLC, a specialty pharmaceutical company focusing on developing and marketing of generic drugs, submits this citizen petition under 21 C.F.R. § 10.30 to request the Commissioner of Food and Drug Administration (FDA) to designate a Reference standard (RS) for Mesalamine Enema 4 g/60 mL.

I. Actions Requested

This petition requests the Commissioner of FDA to take the following actions:

FDA designate the generic product Mesalamine Enema 4 g/60 mL made by PERRIGO ISRAEL PHARMACEUTICALS LTD (ANDA #076751) as the RS since Mesalamine Enema 4 g/60 mL of PERRIGO ISRAEL PHARMACEUTICALS LTD is the only one available in the market at present.

II. Statement of Grounds

A. Introduction

The orange book lists a RLD/RS Rowasa (Mesalamine) Enema 4 g/60 mL approved under NDA 019618 of MYLAN SPECIALTYLP.

RX	MESALAMINE	MESALAMINE	A076751	ENEMA	RECTAL	4GM/60ML	AB			PERRIGO ISRAEL PHARMACEUTICALS LTD
DISCN	MESALAMINE	MESALAMINE	A076841	ENEMA	RECTAL	4GM/60ML				G AND W LABORATORIES INC
RX	MESALAMINE	ROWASA	N019618	ENEMA	RECTAL	4GM/60ML	AB	RLD	RS	MYLAN SPECIALTY LP
RX	MESALAMINE	SFROWASA	N019618	ENEMA	RECTAL	4GM/60ML	AB	RLD		MYLAN SPECIALTY LP

Currently the RLD/RS Rowasa (Mesalamine) Enema 4 g/60 mL approved under NDA 019618 of MYLAN SPECIALTYLP is not available on the market and therefore, Novitium Pharma LLC, requests that FDA promptly designate a RS to facilitate generic drug development.

B. Factual Background

RS is needed for Mesalamine Enema 4 g/60 mL to facilitate product development

The Drug Price Competition and Patent Term Restoration Act (Public Law 98- 417), informally known as the Hatch-Waxman Act, was passed in 1984 by United States Congress to encourage the development of generic products. Compared to brand name products, generic products have the same therapeutic effects on patients, but are generally sold at much lower price. The flourish of generic products greatly reduced the drug price and saved the public healthcare costs. A reference listed drug (RLD) (21 CFR 314.94 (a) (3) means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA. The availability of RLD is critical for generic manufacturer to develop its generic product.

The current orange book lists a RLD/RS Rowasa (Mesalamine) Enema 4 g/60 mL approved under NDA 019618 of MYLAN SPECIALTYLP.

This RLD/RS is not available on the market for generic manufacturers to develop generic version for Mesalamine Enema 4 g/60 mL.

In this regard, Novitium Pharma, submits a citizen's petition requesting FDA designate the generic product made by PERRIGO ISRAEL PHARMACEUTICALS LTD (ANDA #076751) as the RS since Mesalamine Enema 4 g/60 mL of PERRIGO ISRAEL PHARMACEUTICALS LTD is the only one available in the market at present.

Conclusion

For the foregoing reasons, FDA should immediately designate a RS for Mesalamine Enema 4 g/60 mL. The prompt action shall facilitate the generic product development which is beneficial to the reduction of drug price and subsequently, to the reduction of overall public healthcare costs.

C. Environmental Impact

The actions requested in this petition will have no significant effect on the human environment.

D. Economic Impact

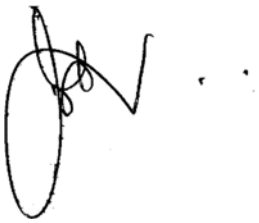
Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

For correspondence, please contact Novitium Pharma LLC, Regulatory Affairs Office by email at RAOffice@novitiumpharma.com, by phone (845) 652-0377 or fax (609) 469-5920.

Thanks,



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