August 28, 2020

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

RE: FDA-2020-P-1775
Withdrawal of ANDA Suitability Petition
Mesalamine Enema 4 g/60 mL

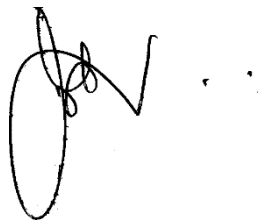
Dear Sir/Madam:

On August 19, 2020, the undersigned submitted a Suitability Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("'FDCA") and 21 C.F.R. §§ 10.20,10.30, and 314.93. The Suitability Petition requested that the Food and Drug Administration ("'FDA'‘) designate the generic product Mesalamine Enema 4 g/60 mL made by PERRIGO ISRAELPHARMACEUTICALS 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.

I herewith withdraw the above-described Suitability Petition. Please terminate the proceeding under Docket FDA-2020-P-1775 since we have learnt now that the RLD ROWASA of MYLAN SPECIALITY LP is back into the market.

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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