May 27, 2022

Maya Kharawala
Alembic Labs LLC
200 Fairfield Avenue
West Caldwell, NJ 07006

Sent via email to: maya@alembic.co.in

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug to make a determination that it is suitable to use a currently approved and marketed generic product as an alternate Reference Listed Drug for performing in vivo bioequivalence study due to the fact that the currently listed Orange book RLD namely, ASACOL HD® (Mesalamine, 800 mg Delayed Release Tablets) of Allergan Pharmaceuticals International Ltd and its authorized generic drug product as well are not available in the interstate commerce from any resources we attempted was received and processed under CFR 10.30 by this office on 05/27/2022.

It was assigned docket number FDA-2022-P-0929. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.05.27 10:50:59 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)