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CITIZEN PETITION

To:

May 27th, 2022

Division of Docket Management
Food & Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir/Madam,

The undersigned from Alembic Labs LLC (USA) hereby submits this citizen petition pursuant to 21 CFR 10.30 and in accordance with 21 CFR 314.94 requesting the Commissioner of Food and Drugs Administration 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.

A. Action Requested

In lieu of absence of current "Orange Book" Reference Listed Drug (RLD) **ASACOL HD®** (Mesalamine, 800 mg Delayed Release Tablets) **(NDA: N021830)** of Allergan Pharmaceuticals International Ltd and its authorized generic product MESALAMINE (TABLETS, DELAYED RELEASE), 800 mg by Zydus Pharmaceuticals USA Inc. approved under same NDA number, Alembic Labs LLC requests FDA to make a determination that generic marketed product MESALAMINE (TABLETS, DELAYED RELEASE), 800 mg distributed/marketed by Zydus Pharmaceuticals USA Inc. under same "**labeler code of 68382**" as authorized generic under ANDA number **A203286** as that of Reference Listed Drug is suitable to use as an alternate Reference Listed Drug (RLD) as the current "Orange Book" RLD **ASACOL HD® (NDA: N021830)** and its authorized generic product is not available in the marketplace.

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Proposed Generic Drug product to designate as RLD

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage form	Route	Strength	TE Code	Applicant Holder
RX	MESALAMINE	MESALAMINE	A203286	TABLET, DELAYED RELEASE	ORAL	800MG	AB	Zydus Pharmaceuticals USA Inc.

B. Statement of Grounds

Mesalamine delayed release tablets, 800 mg is an Oral Dosage Form with active ingredient Mesalamine. Chemically it is aminoasalicylate indicated for the treatment of moderately active ulcerative colitis in adults.

Alembic Labs LLC intends to submit an ANDA for Mesalamine Delayed Release Tablets, 800 mg under pursuant to section 505 U) of FD&C Act and in accordance with 21 CFR 314. Based on Orange Book the innovator for Mesalamine Delayed Release Tablets, 800 mg is Allergan Pharmaceuticals International Ltd and is marketed under the proprietary name **"ASACOL HD®"** registered under NDA number **N021830** and is distributed by Allergan USA, Inc.

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder
RX	MESALAMINE	ASACOL HD	N021830	TABLET, DELAYED RELEASE	ORAL	800MG	AB	RLD	RS	ALLERGAN PHARMACEUTICALS INTERNATIONAL LTD

Zydus Pharmaceuticals USA Inc. has authorized generic for "Mesalamine" registered under the same NDA number **N021830** (as per Daily Med **NDC 68382-484-28 is inactivated** for authorized generic) and product is not available in marketplace.

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7a7d8d3c-d407-4864-b305-e83c036fe98c&audience=consumer

Attachment I from Daily Med for Authorized Generic Product)

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Zydus Pharmaceuticals USA Inc also have generic version marketed under same NDC labeler code as authorized generic product (NDC Labeler code 68382)
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ad8c7930-92e2-4372-a874-da22b9ae333e&audience=consumer

(Attachment II from Daily Med for Generic Product)

The FDA's website (drug @ FDA) and the current edition of the "Orange Book" lists Mesalamine Delayed Release Tablets, 800 mg as Reference Listed Drug and shows that drug product has not been officially discontinued by Allergan Inc. **(Attachment II from Daily Med)**. The wholesale distributors contacted have repeatedly indicated that Allergan's Mesalamine Delayed Release Tablets, 800 mg is not available for commercial distribution from Allergan, Inc. Neither authorized generic from Zydus Pharmaceuticals USA Inc. is available from several resources contacted across the nation (geographically) and at various stages of supply chain of the drug distribution, starting at the retail pharmacies to the drug distributors & wholesalers.

Reference is also made to FDA's response to citizen petition **(Attachment III)** dated July 03, 2013 (Petition with Docket No. FDA-2013-P-0040) which indicates that ***"An ANDA applicant may use the authorized generic version of the current RLD as the reference standard in the in vivo bioequivalence study with proper documentation, because the RLD is still available as an authorized generic"***

(Attachment III: FDA's response to citizen petition dated July 03, 2013)
(Docket No: FDA-2013-P-0040)

In conclusion, for the reason stated above in this statement of grounds, Alembic Labs LLC-USA requests FDA to make a determination that generic marketed product Mesalamine Delayed Release Tablets, 800 mg distributed by Zydus Pharmaceuticals USA Inc. under generic version under ANDA number **A2032863** distributed under same labeler code (62382) is suitable to use as an alternate Reference Listed drug (RLD) as the current Orange Book RLD **ASACOL HD®** (Mesalamine, 800 mg Delayed Release Tablets) **(NDA: N021830)** and its authorized generic version product is also not available in the marketplace.

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C. Environmental Impact

Under 21CFR §25.3l(a), this petition qualifies for a categorical exemption from the requirements to submit an environmental assessment.

D. Economic Impact

According to 21 CFR § 10.30 (b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

E. Certification

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

If we can be of any further assistance, please do not hesitate to call us at (973) 226-3700 x 104 or write us at maya@alembic.co.in.

Sincerely,

Maya Kharawala

Digitally signed by Maya Kharawala
Date: 2022.05.27 09:02:48 -04'00'

Ms. Maya Kharawala, Vice President, ARD/Quality/Regulatory
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