



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF 029958

DMF ACKNOWLEDGEMENT

ALUTECH PACKAGING PVT. LTD.
ATTENTION: RAKESH GOEL
RIDA, DEHKORA ROAD, VILLAGE ROHAD
BAHADURGARH-124107, HARYANA, INDIA

Dear Rakesh Goel,

The Food And Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF Number Assigned : 029958
Date Of Submission : AUGUST 24, 2015
DMF TYPE: II
Subject (Title): ALU-ALU FOIL (SILPACK)TM, BLISTER FOIL, STRIP FOIL PLAIN, COLORED AND PRINTED
Holder: ALUTECH PACKAGING PVT. LTD.
Submitted By: ALUTECH PACKAGING PVT. LTD.
Agent: PERFECT PHARMACEUTICAL CONSULTANTS PVT. LTD.

All subsequent correspondence to this DMF should be identified with the information as provided above. One original and one duplicate copy should be submitted to the following address.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Drug Master File Staff
5901-B Ammendale Road
Beltsville MD 20705-1266

You are advised that all DMFs must be in electronic format as of May 5, 2017. See the "Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications."

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf>. Paper submissions to a DMF will not be accepted after that date. Electronic submissions must be submitted in eCTD format, through the Electronic Submission Gateway (ESG) or on physical media (such as compact disc) mailed to the above address. Note that, according to the Guidance "For all submissions that are 10 gigabytes (GB) or smaller, you must use the FDA ESG".

Reference ID: 3842511