DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

DMF 037478

**DMF ACKNOWLEDGEMENT**

AGI GREENPACK LTD - AGI SPECIALITY GLASS DIVISION
ATTENTION: MR. DHEERAJ KUMAR, AVP - QA & SYSTEMS
GLASS FACTORY ROAD
OFF MOTINAGARM, BORABANDA
HYDERABAD - 500018, INDIA

Dear Mr. Dheeraj Kumar,

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

| | |
|---|---|
| **DMF NUMBER ASSIGNED:** | 037478 |
| **DATE OF SUBMISSION:** | SEPTEMBER 5, 2022 |
| **DMF TYPE:** | III |
| **SUBJECT (TITLE):** | SPECIALTY GLASS CONTAINERS (USP) FOR PACKING OF PHARMACEUTICAL, FOOD AND COSMETIC PRODUCTS |
| **HOLDER:** | AGI GREENPACK LTD - AGI SPECIALITY GLASS DIVISION |
| **SUBMITTED BY:** | AGI GREENPACK LTD - AGI SPECIALITY GLASS DIVISION |
| **AGENT:** | PERFECT PHARMACEUTICAL CONSULTANTS PVT. LTD. |

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection to a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

For information on various DMF submissions, example of letter templates and DMF Guidance for Industry, check the DMF website at https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs

The holder of the DMF is responsible for compliance with 21 CFR314.420 as interpreted in "The Guideline for Drug Master Files" at https://www.fda.gov/drugs/drug-master-files-dmfs/guideline-drug-master-files-dmf

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
    a. Letters of Authorization (LOAs) granting permission to a third party (authorized party) or self to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report is not sufficient to authorize that party to reference the DMF. Submission of a copy of the LOA to the authorized party without submitting the original LOA to the DMF (with DMF number) is also not sufficient to authorize that party to reference the DMF.
    b. Any change, addition or deletion of information
    c. Annual Reports to the DMF containing:
        i. Date(s) of the amendment(s) reporting changes since the last Annual Report or the original DMF filing date, whichever is most recent or a statement that no amendments have been submitted since the last Annual Report or the original DMF filing date, whichever is most recent.
        ii. A complete list of all parties currently authorized to incorporate information in the DMF by reference; identifying by name, reference number, volume, date, and page number the information that each person is authorized to incorporate and the date of the LOA or a statement that there are no Authorized Parties.
        iii. A list of all parties whose authorization has been withdrawn, if applicable.
        iv. Holder signed DMF Statement of Commitment stating that the DMF is current and the holder will comply with the statements made in it.

Electronic submissions that are 10GB or smaller in size must be submitted through the Electronic Submission Gateway (ESG). Submissions that are over 10GB may be submitted on physical media (such as compact disc) 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

See FDA eCTD Web Page[1] and Guidance for Industry on electronic submissions[2] for information.

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[1] See FDA eCTD Web Page for further information. https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd

[2] Section 745A(a) of the Food, Drug, and Cosmetic Act. See "Guidance for Industry: Providing Regulatory Submissions in Electronic Format —Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (April 2017). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications-0

For question on DMF submissions, send an email to dmfquestion@fda.hhs.gov

Sincerely yours,

*{See appended electronic signature page}*

David Skanchy, Ph.D.
Director, Division of Lifecycle API
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

CC:
PERFECT PHARMACEUTICAL CONSULTANTS PVT. LTD.
ATTENTION: MR SUMIT GUPTA, DIRECTOR
PRESTIGE CLASSIC BLD., D-WING OFF. G4 & 5
CHINCHWAD STATION, PUNE-411019, MAHARASHTRA, INDIA

**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

/s/

CLAUDE THEOPHIN
09/12/2022 01:46:05 PM