



DMF 29515

DMF ACKNOWLEDGEMENT

FORTCAPS HEALTHCARE LIMITED
ATTENTION: MRS. MEENU KAUSHIK
GROUND FLOOR A-7, COMMUNITY CENTRE
NARAINA VIHAR, NEW DELHI - 110028, INDIA

Dear Mrs. Meenu Kaushik,

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

DMF Number Assigned: 29515
Date of Submission: AUGUST 12, 2015
DMF Type: IV
Subject (Title): EMPTY HARD GELATIN CAPSULES
Holder: FORTCAPS HEALTHCARE LIMITED
Submitted by: FORTCAPS HEALTHCARE LIMITED
Agent: PERFECT PHARMACEUTICAL CONSULTANTS PVT. LTD

All subsequent correspondence to this DMF should be identified with the information as provided above. Electronic submissions should be submitted in an eCTD format, through Electronic Submission Gateway (ESG) or on physical media (such as compact disc) mailed to the following address:

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

Your DMF will be reviewed only in connection with 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.

You are responsible for compliance with 21 CFR314.420. See "The Guideline for Drug Master Files" <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073164.htm>