DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF 031255

DMF ACKNOWLEDGEMENT

SHREE NAINA PACKWELL INC.
ATTN: JAGMOHAN KHANNA, MANAGING PARTNER
VILLAGE KATHA, P.O BADDI
DIST. SOLAN - 173205, HIMACHAL PRADESH, INDIA

Dear Jagmohan Khanna,

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

DMF NUMBER ASSIGNED:	031255
DATE OF SUBMISSION:	DECEMBER 20, 2016
DMF TYPE:	III
SUBJECT (TITLE):	GLASS AMPOULES AND VIALS & DENTAL CARTRIDGE
HOLDER:	SHREE NAINA PACKWELL INC.
SUBMITTED BY:	SHREE NAINA PACKWELL INC.
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 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

You are required to submit all changes in information regarding the DMF (21 CFR 314.420(c)). In particular the FDA must be notified of any changes in the holder name or ownership and/or the agent and/or the name of the contact person.