DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF ACKNOWLEDGEMENT LETTER

SUNIL HEALTHCARE LTD
Attn: SABYASACHI NATH
38E/252-A VIJAY TOWER,
OPP. PANCHSHEEL PARK COMM. COMPLEX,
NEW DELHI - 110049, INDIA

Dear SABYASACHI NATH,

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

DMF Number Assigned:	025979
Date of Submission:	05/05/2012
DMF Type:	IV
Subject:	EMPTY HARD GELATIN CAPSULES as manufactured in RAJASTHAN, INDIA
Holder:	SUNIL HEALTHCARE LIMITED
Submitted by:	SUNIL HEALTHCARE LIMITED
Agent:	ECODESIGN WORLD

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

Your DMF will be reviewed only in connection with a New Drug Applications, 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.

You are responsible for compliance with the Regulation Title 21 Code of Federal Regulations Part 314.420 as interpreted in "The Guideline for Drug Master Files" [HEW (FDA) 79-3072.

See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide to the FDA by submission to the DMF in two copies.