DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration Silver Spring, MD 20993

DMF 033290

DMF ACKNOWLEDGEMENT

SUNPURE EXTRACTS PVT. LTD.
Attention:

E-25, INDUSTRIAL AREA, SIKANDRABAD - 203205
UTTAR PRADESH, INDIA

Dear Sir,

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

DMF NUMBER ASSIGNED:	033290
DATE OF SUBMISSION:	OCTOBER 23, 2018
DMF TYPE:	II
SUBJECT (TITLE):	BOSWELLIA SERRATA EXTRACT (AKBA-30%)
HOLDER:	SUNPURE EXTRACTS PVT. LTD.
SUBMITTED BY:	SUNPURE EXTRACTS 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.

The types of information to be submitted may be found at the DMF Web Site: www.fda.gov/cder/dmf. See "**Submission of Amendments, Annual Reports, and Letters of Authorization.**