DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF 032331

DMF ACKNOWLEDGEMENT

SILVERLINE CHEMICALS
ATTN: MR. RAMAN SHINGLA, MANAGING DIRECTOR
SHINGLA CARPETS BLDG, GT ROAD, NEAR TEHSIL
PANIPAT-132103, HARYANA, INDIA

Dear Mr. Raman Shingla,

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

DMF NUMBER ASSIGNED:	032331
DATE OF SUBMISSION:	FEBRUARY 12, 2018
DMF TYPE:	IV
SUBJECT (TITLE):	LEVO-MENTHOL USP/BP/EP/IP/JP
HOLDER:	SILVERLINE CHEMICALS
SUBMITTED BY:	SILVERLINE CHEMICALS

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. See "**Submission of Amendments, Annual Reports, and Letters of Authorization.**

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:

Reference ID: 4220573