DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF 29751

DMF ACKNOWLEDGEMENT

HENAN LIHUA PHARMACEUTICAL CO., LTD.
Attention: ZHIGANG NIU, QUALITY DIRECTOR
MIDDLE OF HUANGHE STREET, ANYANG, HI-TECH
INDUSTRY DEVELOPMENT ZONE, HENAN 455 100, CHINA

Dear Zhigang Niu,

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

DMF Number Assigned:	29751
Date of Submission:	SEPTEMBER 22, 2015
DMF Type:	II
Subject (Title):	PREDNISOLONE SODIUM PHOSPHATE USP
Holder:	HENAN LIHUA PHARMACEUTICAL CO., LTD.
Submitted by:	ACETO CORPORATION
Agent:	ACETO CORPORATION

All subsequent correspondence to this DMF should be identified with the information as provided above. One original and one duplicate copy should be submitted to the following address.

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

You are advised that all DMFs must be in electronic format as of May 5, 2017. See the "Guidance for Industry: Providing Regulatory Submissions in Electronic Format —Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications." http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf. Paper submissions to a DMF will not be accepted after that date. Electronic submissions must be submitted in eCTD format, through the Electronic Submission Gateway (ESG) or on physical media (such as compact disc) mailed to the above address. Note that, according to the Guidance "For all submissions that are 10 gigabytes (GB) or smaller, you must use the FDA ESG".
See "Specification for Transmitting Electronic Submissions using eCTD"
http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163567.pdf

See the DMF Web Site: www.fda.gov/cder/dmf for the mailing address for submissions on physical media.

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:
    a. Letters of Authorization (LOAs) granting permission to a third party (authorized party) to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report (see below) is not sufficient to authorize that party to reference the DMF. Submission of a copy of the LOA to the authorized party without submitting the original LOA to the DMF is also not sufficient to authorize that party to reference the DMF.
    b. Annual Reports to the DMF containing:
        i. Date(s) of the amendment(s) reporting changes since the last Annual Report or the original DMF filing date, whichever is most recent or a statement that no amendments have been submitted since the last Annual Report or the original DMF filing date, whichever is most recent.
        ii. A complete list of all parties authorized to make reference to the DMF, identifying by name, reference number, volume, date, and page number the information that each person is authorized to incorporate and the date of the LOA or a statement that there are no Authorized Parties.
        iii. A list of all parties whose authorization has been withdrawn, if applicable.

Submissions containing multiple types of information e.g. administrative changes, an annual report, or changes in technical information should specify the different types of information in the header in the cover letter.

If you submitted an LOA without the DMF number with the original submission, please resubmit the LOA with the DMF number.

Please refer to the DMF website www.fda.gov/cder/dmf for information on DMF submissions and examples of letter templates.

If you have any questions, please email dmfquestion@fda.hhs.gov

Sincerely,
{See appended electronic signature page}
Vathsala Selvam
Technical Information Specialist
Drug Master File/DLCAPI/ONDP/OPQ
Center for Drug Evaluation and Research
Food and Drug Administration

CC:
ACETO CORPORATION
Attn: ELLEN WATERMAN
4 TRI HARBOR COURT
PORT WASHINGTON, NY 11050

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CLAUDE THEOPHIN
10/01/2015