



DMF 28066

**DMF ACKNOWLEDGEMENT-REGULAR**

HENAN LIHUA PHARMACEUTICAL CO., LTD.  
Attention: ZHIGANG NIU,  
GENERAL MANAGER ASSISTANT AND QA MANAGER  
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:** 28066  
**Date of Submission:** FEBRUARY 28, 2014  
**DMF Type:** II  
**Subject (Title):** HYDROCORTISONE USP as manufactured in HENAN, CHINA  
**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 and, if in paper, should be submitted in duplicate 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

Electronic submissions on disc should be submitted in an eCTD format to the same address. Electronic submissions can also be submitted through the Electronic Submission Gateway.

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 when a Letter of Authorization is submitted to 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>

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CLAUDE THEOPHIN  
03/10/2014

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CC:

ACETO CORPORATION

Attn: DR. DAVID V. PETROCINE

4 TRI HARBOR COURT

PORT WASHINGTON, NY 11050

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](http://www.fda.gov/cder/dmf)  
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.

If you have any questions, please email [dmfquestion@cder.fda.gov](mailto:dmfquestion@cder.fda.gov)

Sincerely,

*{See appended electronic signature page}*

Vathsala Selvam

Technical Information Specialist

Drug Master File

Immediate Office/Office of Pharmaceutical Science

Center for Drug Evaluation and Research