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Health Canada  
Therapeutic Products Directorate  
DMF Administration Unit  
Address Locator 0201D  
101 Tunney's Pasture Driveway  
Ottawa, Ontario  
K1A 0K9  
Canada

**DMF 2015-135**

**HC6-24-F2015135**

August 11, 2015

Niu Zhigang  
QA Manager  
HENAN LIHUA PHARMACEUTICAL CO., LTD.  
Middle of Huanghe Street  
Anyang Hi-Tech Industry Development Zone  
Henan, China

Dear Sir or Madam Zhigang:

**RE: Prednisolone Acetate**

We are acknowledging receipt of your letter dated **July 2, 2015** and the material listed below for Prednisolone Acetate, which has been assigned the number DMF 2015-135.

Drug Master Files (DMFs) will only be reviewed in connection with drug submissions from sponsors for whom you have provided a letter of authorization; therefore, this acknowledgement should not be considered as an approval of the content of your Drug Master File.

Please note that Health Canada has received the following:

1. Payment of **\$424.00 Cdn.** for new Drug Master File registration
2. 1 binder "Open Part"
3. 1 binder "Closed Part"
4. 1 CD "Quality Overall Summary"
5. Letter of Access and Fees for sponsor (see attached Acknowledgement Letter)
6. Statement of commitment
7. BSE/TSE Attestation

Please refer to the Health Canada website for the new amended fees as of April 1<sup>st</sup>, 2015, including the stipulation of a new two percent annual increase effective each April 1<sup>st</sup>.

<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/fees-frais/index-eng.php#master>

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**Health Canada is moving toward an electronic format for Drug Master Files; as such, we would appreciate a copy of your Drug Master File(s) and subsequent updates to be sent as PDF files on a CD to supplement the paper copy. Please also include an attestation confirming the hard copy is identical to the electronic copy.**

We would like to take this opportunity to remind DMF Owners and Agents that they are responsible for all costs associated with shipping documents and electronic information to Health Canada, including any applicable customs and/or brokerage fees. Packages must indicate "**Terms DDP (Delivered Duty Paid)**". Any packages submitted to Health Canada with a request for additional charges by a shipper or brokerage firm will be returned to sender at the sender's expense. Thank you for your attention to this matter.

For Type I DMFs (pertaining to active pharmaceutical ingredients), you are reminded that a copy of the open part must be provided to the sponsor of a drug submission that cross-references the DMF.

The open part of Type I DMFs may, therefore, be subject to discussions between the Therapeutic Products Directorate (TPD) and the submission sponsor for whom you have authorized Health Canada to access your DMF.

The closed part of Type I DMFs and all parts of Types II, III and IV DMFs will be kept confidential.

If any comments are considered necessary concerning the closed part of Type I DMFs or all parts of Types II, III and IV DMFs, they will be forwarded directly to the DMF Owner. In this case, the submission sponsor may be notified that there are outstanding issues that must be addressed before the DMF can be considered to support their drug submission.

It is recommended that Drug Master Files be **updated** every two years in order to keep these files open and active. Any changes or additions to the Drug Master File should be forwarded to the DMF Administration Unit as soon as possible.

\*Please note that the Therapeutic Products Directorate (TPD) of the Health Products and Food Branch (HPFB) of Health Canada is now accepting Certificates of Suitability (CEPs) issued for Active Pharmaceutical Ingredients (APIs) by the European Directorate for the Quality of Medicines and HealthCare (EDQM). Please consult the website below for more information.

[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/int/edqm\\_2007-eng-php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/int/edqm_2007-eng-php) (in English)

[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/int/edqm\\_2007-fra-php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/int/edqm_2007-fra-php) (in French)

If you have further questions on the administration of the Drug Master Files, please e-mail [dmf\\_enquiries@hc-sc.gc.ca](mailto:dmf_enquiries@hc-sc.gc.ca).

Yours sincerely,

*Tania-Elena Di Millo-Briganti*

DMF Administration Unit