



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF ACKNOWLEDGEMENT LETTER

SUZHOU HAISHUN PACKAGING MATERIAL CO., LTD.
Attention: MR. WUHUI LIN, GENERAL MANAGER
NO. 118, LAIXIU RD, FENHU, WUJIANG
SUZHOU, P.R. CHINA
POSTCODE 215211

Dear: MR. WUHUI LIN,

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

DMF Number Assigned: 024534
Date of Submission: 12/15/2010
DMF Type: III
Subject: PCTFE/PVC COMPOSITE SHEET FOR PHARMACEUTICAL
PACKAGING as manufactured in SUZHOU, P.R. CHINA
Holder: SUZHOU HAISHUN PACKAGING MATERIAL CO., LTD.
Submitted by: SUZHOU HAISHUN PACKAGING MATERIAL CO., LTD.
Agent(s): BEIJING CANNY CONSULTING INC.

All subsequent correspondence to this DMF should be identified with the information as provided above and should be submitted in duplicate.

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.

You are responsible for compliance with the Regulation Title 21 Code of Federal Regulations Part 314.420 as interpreted in "The Guideline for Drug Master Files" [HEW (FDA) 79-3072.

See

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm>.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide to the FDA by submission to the DMF in two copies:
 - ❖ 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

Reference ID: 2893490

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 two copies to the DMF is also not sufficient to authorize that party to reference the DMF.

- ❖ Amendments to the DMF. The types of information to be submitted may be found at the DMF Web Site under <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm>

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

- ❖ Annual Reports to the DMF containing:
 - a list of all changes and additional information incorporated into the DMF since the previous annual report on the subject matter of the DMF. If the subject matter of the DMF is unchanged, provide a statement that the subject matter of the DMF is current.
 - a list of all persons authorized to make reference to the DMF, identifying by name (or code) the information that each person is authorized to incorporate and giving the location of that information by date, volume, and page number. If the list is unchanged on the anniversary date, submit a statement that the list is current.
 - identification of any party whose authorization has been withdrawn

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, contact Sharon.Brownewell@fda.hhs.gov or at (301) 301-796-0577.

Sincerely,

Sharon L. Brownewell
Manager, CDER Drug Master Files
Office of Business Informatics (OBI)
Office of Planning Informatics (OPI)
Center for Drug Evaluation and Research

CC: BEIJING CANNY CONSULTING INC.
ATTN: MR. PENGCHENG KANG
RM. 2405 BUILDING C, OCEAN INTERNATIONAL CENTER
NO. 60 4TH EAST RING CENTRE ROAD, CHAOYANG DISTRICT
BEIJING, PEOPLE'S REPUBLIC OF CHINA, POSTCODE 100025

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

/s/

VATHSALA D SELVAM on behalf of SHARON L BROWNEWELL
01/19/2011