



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF 030126

DMF ACKNOWLEDGEMENT

CHIN-TAI PHARMACEUTICAL PLASTIC, LTD
ATTENTION: MR. HAUNG-CHEN HUANG
NO. 629, TE-MEI ROAD, HO-MEI CHEN,
CHANG-HUA HSIEN, 50851 TAIWAN, R.O.C.

Dear Mr. Huang-Chen Huang,

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

DMF Number Assigned: 030126
Date of Submission: DECEMBER 4, 2015
DMF Type: III
Subject (Title): PHARMACEUTICAL BOTTLES AND CLOSURES
Holder: CHIN-TAI PHARMACEUTICAL PLASTIC, LTD
Submitted by: CHIN-TAI PHARMACEUTICAL PLASTIC, LTD
Agent: EAST WIND PHARMACEUTICALS LLC

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

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.

Currently, there is no requirement to submit or resubmit DMFs in any electronic format. However, beginning on May 5, 2017, new DMFs, as well as subsequent submissions to previously submitted