

Food and Drug Administration Silver Spring MD 20993

DMF 032228

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: (

032228

DATE OF SUBMISSION:

NOVEMBER 3, 2017

DMF TYPE:

III

SUBJECT (TITLE):

OPHTHALMIC DROPPER BOTTLES

HOLDER:

CHIN-TAI PHARMACEUTICAL PLASTIC, LTD

SUBMITTED BY:

CHIN-TAI PHARMACEUTICAL PLASTIC, LTD

AGENT:

EAST WIND PHARMACEUTICS LLC

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

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.