DMF 041704

**DMF ACKNOWLEDGEMENT**

ZHANGJIAGANG ZHONGHUI MEDICAL PLASTIC TECHNOLOGY LTD., CO.
ATTENTION: HUI WANG, GENERAL MANAGER
BUILDING 50, LIN RUI ZHI ZAO INDUSTRIAL, PART, NO. 99
MIAOQIAO CHUIGU ROAD, TANGQIAO TOWN, ZHANGJIAGANG CITY
JIANGSU PROVINCE, 215600 P.R. CHINA

Dear Hui Wang,

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

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|---|---|
| **DMF NUMBER ASSIGNED:** | 041704 |
| **DATE OF SUBMISSION:** | MARCH 26, 2025 |
| **DMF TYPE:** | III |
| **SUBJECT (TITLE):** | OPHTHALMIC ANTIBACTERIAL MULTI-DOSE DRUG DELIVERY SYSTEM |
| **HOLDER:** | ZHANGJIAGANG ZHONGHUI MEDICAL PLASTIC TECHNOLOGY LTD., CO. |
| **SUBMITTED BY:** | ZHANGJIAGANG ZHONGHUI MEDICAL PLASTIC TECHNOLOGY LTD., CO. |
| **AGENT:** | NONE |

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

Your DMF will be reviewed only in connection to 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.

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
  - Letters of Authorization (LOAs) granting permission to a third party (authorized party) or self to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report is not sufficient to authorize that party to