

Food and Drug Administration Silver Spring MD 20993

DMF 032219

DMF ACKNOWLEDGEMENT

PIONEER EXTRUDERS PVT. LTD.
ATTENTION: MR. KISHORE PATEL, MANAGING DIRECTOR
120 MORYA IND. ESTATE, NEW LINK ROAD
OPP. INFINITY MALL, ANDHRI (W), MUMBAY-400053, INDIA

Dear Mr. Kishore Patel,

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

DMF NUMBER ASSIGNED: 032219

DATE OF SUBMISSION: OCTOBER 3, 2017

DMF TYPE:

SUBJECT (TITLE):

ALUMINIUM AEROSOL CANS
PIONEER EXTRUDERS PVT. LTD.

SUBMITTED BY: PIONEER EXTRUDERS PVT. LTD.

AGENT: NONE

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.

Currently, there is no requirement to submit or resubmit DMFs in any electronic format. However, starting May 5, 2018, new DMFs, as well as any submissions to the existing DMFs must be submitted electronically in eCTD (electronic Common Technical Document) format specified by FDA in the