DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF ACKNOWLEDGEMENT LETTER

SHREE RAMA MULTI-TECH LTD.
Attn: MR. ANKIT P. SHAH
603, SHIKHAR BUILDING, NETAJI MARG, NAVRANGPURA
AHMEDABAD 380 009, GUJARAT, INDIA

Dear MR. ANKIT P. SHAH,

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

DMF Number Assigned:	26821
Date of Submission:	01/17/2013
DMF Type:	III
Subject:	LAMI TUBES as manufactured in GUJARAT, INDIA
Holder:	SHREE RAMA MULTI-TECH LTD.
Submitted by:	SHREE RAMA MULTI-TECH LTD.
Agent:	NONE

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