DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF ACKNOWLEDGEMENT LETTER

CHEMIPACK (INDIA) PRIVATE LIMITED
Attention: DR. D. MOHAN RAO, MANAGING DIRECTOR
8-3-166/6 & 7, II FLOOR, SREE ARCADE
ERRAGADDA, HYDERABAD - 500018
ANDHRA PRADESH, INDIA

Dear: DR. D. MOHAN RAO

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

DMF Number Assigned:	**25241**
Date of Submission:	08/16/2011
DMF Type:	III
Subject:	'HDPE BOTTLE' as manufactured in ANDHRA PRADESH, INDIA
Holder:	CHEMIPACK (INDIA) PRIVATE LIMITED
Submitted by:	CHEMIPACK (INDIA) PRIVATE LIMITED
Agent(s):	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 party) to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report (see below) is not sufficient to authorize that party to

reference the DMF. Submission of a copy of the LOA to the authorized party without submitting two copies to the DMF is also not sufficient to authorize that party to reference the DMF.

- Amendments to the DMF. The types of information to be submitted may be found at the DMF Web Site under http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm

  See "**Submission of Amendments, Annual Reports, and Letters of Authorization.**"

- Annual Reports (Annual updates) to the DMF containing:
  - a list of all changes and additional information incorporated into the DMF since the previous annual report on the subject matter of the DMF. If the subject matter of the DMF is unchanged, provide a statement that the subject matter of the DMF is current.

  - a list of all persons authorized to make reference to the DMF, identifying by name (or code) the information that each person is authorized to incorporate and giving the location of that information by date, volume, and page number. If the list is unchanged on the anniversary date, submit a statement that the list is current.

  - identification of any party whose authorization has been withdrawn

Submissions containing multiple types of information e.g. administrative changes, an annual report, or changes in technical information should specify the different types of information in the header in the cover letter.

If you submitted an LOA without the DMF number with the original submission, please resubmit the LOA with the DMF number.

If you have any questions, contact Vathsala Selvam or Scott Zeiss at (301)796-0585 or (301)796-0639 respectively, or by email at vathsala.selvam@fda.hhs.gov or scott.zeiss@fda.hhs.gov.

Sincerely,

Franklin Stephenson, M.S.
Supervisor, Records Management Team
Division of Records Management
Office of Business Informatics, CDER, FDA
franklin.stephenson@fda.hhs.gov

CC:

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SCOTT E ZEISS on behalf of FRANKLIN T STEPHENSON
08/31/2011