DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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RELIANCE INDUSTRIES LIMITED
Attn: Dr. Y.B. Vasudeo, Sr. Vice President
Product Application & Research Centre (PARC)
Swastik Mill Compound
V.N. Purav Marg, Chembur
Mumbai 400 071, INDIA

MAY 17 2005

Dear Sir/Madam:

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

DMF Number Assigned: 18324 **Date of Submission:** April 28, 2005
DMF Type: III
Title of Submission: Polyethylene (PE) Relene B56003 Raw Material **as manufactured in** Gujarat, India
Holder of Submission: Reliance Industries Limited
Submitted by: Reliance Industries Limited
Agent(s): None

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

Your DMF will be reviewed only in connection with the New Drug Applications, Abbreviated New Drug Applications, Investigational New Drug Applications or any DMFs it is intended to support.

The holder of the DMF is 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]. This information can be found at www.fda.gov/cder/guidance/index.htm. This includes adhering to the statement of the commitment and providing the FDA with the following:

- an annual list of all individuals and firms authorized to make reference to the DMF and identification of any party whose authorization has been withdrawn;
- an annual update of the DMF or a statement that the DMF remains current(whichever is appropriate); and
- amendments which incorporate any changes in the DMF. Parties authorized to reference the DMF should be notified of the changes before implementation.

Sincerely,

Scott E Zein
FOR

Sharon L. Brownewell
Public Health Analyst
Manager of Drug Master Files
Office of Information Management
Records Repository Team

CC: Chron DMF 18324 **Orig.,Dup.**