DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ERAWAT PHARMA LIMITED
Attn: Mr. Abhishek Jain
Director
512, Industrial Area No. 3
Pithampur, Dist - Dhar
Pithampur - 454 774, INDIA

AUG - 2 2004

Dear Sir/Madam:

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

DMF Number Assigned:17515 Date of Submission: June 28, 2004
DMF Type: IV
Title of Submission: Empty Hard Gelatin Capsules as manufactured in Pithampur, India
Holder of Submission: Erawat Pharma Limited
Submitted by: Erawat Pharma 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and firms authorized to make reference to the DMF and identification of any party whose authorization has been withdrawn;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,

Sharon L. Brownewell

Sharon L. Brownewell
Technical Information Specialist
Drug Master File Liaison
Office of Information Management
Records Management Team

CC:Chron
DMF 17515 Orig.,Dup.