



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
International Compliance Team
10903 New Hampshire Ave
WO51, Room 4242
Silver Spring, Maryland 20993

TELEPHONE: (301) 796-3120
FAX: (301) 847-8741

May 5, 2008

Mr. Ashok Jhaveri
Director – Technical
Mega Fine Pharma Limited
Sethna 4th Floor
55 Maharshi Karve Road
Marine Lines, Mumbai – 400 002 India

Dear Mr. Jhaveri:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical ingredient (API) manufacturing site in Vapi, Gujarat, India on 2/29-3/1/08 by FDA Investigator Tara R. Goen and Chemist Guo Q. Shen.

Based on this inspection, we are classifying this facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices. Additionally, there were 6 verbal deficiencies discussed with you at the conclusion of the inspection. We expect these deficiencies to be fully corrected by the time commercial production commences. Corrective actions will be verified during the next inspection of your facility.

Additionally, we have enclosed a copy of the Establishment Inspection Report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at 10903 New Hampshire Avenue, WO51, Room 4234, Silver Spring, MD 20993. You may also contact me by telephone at 301-796-3206 or by email at Alicia.Mozzachio@fda.hhs.gov.

Sincerely,

Alicia M. Mozzachio
Compliance Officer

Enclosure: