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 Branch
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June 12, 2012

Mr. Narendra Salvi
Director
Aarti Industries
71, Udyog Kshetra, 2nd Floor
Mulund Goregaon Link Rd.
Mulund (W), Mumbai
India, 400080

Dear Mr. Salvi:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your Active Pharmaceutical Ingredient facility in Tarapur, Tal-Palghar, India by Investigator Patric C. Klotzbuecher on 09/26/2011 through 10/05/2011. The inspection noted a deficiency listed on the FDA-483 Inspectional Observations Form, issued to you at the conclusion of the inspection.

We acknowledge receipt of your written response dated November 08, 2011 and of your follow-up correspondence dated March 29th, 2012. According to your response to the noted inspectional observation in the FDA-483 Form the proposed corrective action has been completed. The corrective action appears to have addressed adequately the noted observation. Based on our review of the commitment and corrective action being implemented and the profile class covered during the inspection, we are classifying your facility as acceptable. Your corrections will be verified during the next inspection of your facility. 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 (CGMPs).

Additionally, we enclose 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 the above address or number.

Sincerely,

Cesar E. Matto
Compliance Officer
Office of Manufacturing and Product Quality
Division of International Drug Quality

Enclosure: EIR