



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Compliance
Division of Manufacturing and Product Quality
International Compliance Branch
White Oak, Building 51
10903 New Hampshire Avenue,
Silver Spring, MD 20993

July 21, 2009

Dr. V. Satyanarayana
Managing Director
Sipra Labs
7-2-1813/5/A, Adjacent to Post Office
Industrial Estate, Sanathnagar, Hyderabad
500 018, India

Dear Dr. Satyanarayana:


FDA has completed the review of the Establishment Inspection Report (EIR) for the inspection conducted at your contract testing laboratory facility in Hyderabad, India, on April 15-17, 2009, by FDA Investigator Azza Talaat. An FDA-483 was issued to you at the conclusion of the inspection.

We also reviewed your firm's response letter dated June 09, 2009 with supportive documentation. We are classifying your laboratory facility as acceptable for contract testing. However, it remains your firm's responsibility to ensure continued compliance with current good manufacturing practices. This letter is not intended as an endorsement or certification of the facility.

Additionally, we 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 the above address or telephone numbers.

Sincerely,


Hidee L. Molina

Compliance Officer/Chemist
International Compliance Branch

Enclosure: