



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality  
Division International Drug Quality  
International Compliance Branch  
10903 New Hampshire Avenue  
Building #51, Room 2258  
Silver Spring, MD 20993

TELEPHONE: (301) 796-0483  
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September 7, 2012

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

Reference: FEI 3004544153

Dear Dr. Satyanarayana:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your contract testing laboratory in Sanathnagar, Hyderabad, India by Investigator Heriberto Negron-Rivera during the period of September 26 to 28, 2011. An FDA-483, Notice of Inspectional Observations was issued at the conclusion of the inspection.

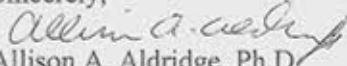
We have also reviewed your company's responses dated October 19, 2011, and September 1, 2012, with supportive documentation. Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practice (CGMP).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at [http://www.fda.gov/cder/drls/registration\\_listing.htm](http://www.fda.gov/cder/drls/registration_listing.htm)

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 Freedom of Information Act and 21 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,

  
Allison A. Aldridge, Ph.D.  
Compliance Officer

Division of International Drug Quality

Enclosure: EIR