



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Quality Surveillance Assessment  
Inspection Assessment Branch  
10903 New Hampshire Avenue  
Building #51, Room 3221A  
Silver Spring, MD 20993

TELEPHONE: (240) 402-4478  
FAX: (301) 847-8742

11/04/2015

Mr. Akshay Gupta  
FirstSource Laboratory Solution LLP  
First Floor, Plot No. A1/B  
IDA Nacharam Cross Road  
Hyderabad 500076  
Telangana, India

Reference FEI 3007308467

Reference inspection date (s): 07/15-16/2015

Establishment Locale: First Floor, Plot No. A1/B IDA Nacharam Cross Rd Hyderabad, India

Dear Mr. Gupta,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at the above address or number.

Sincerely,

**Teresa I.  
Navas -S**

Digitally signed by Teresa I. Navas  
-S  
DN: cn=LIS, ou=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
o=U.S.2342.19200100.100.1.1-2000  
379663, cn=Teresa I. Navas -S  
Date: 2015.11.04 09:23:25 -05'00'

Teresa I. Navas, M.S.  
Consumer Safety Officer  
Inspection Assessment Branch

Enclosure: EIR

Cc: