DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

VIA UPS

November 21, 2014

Lalitha Kamath
Manager-Quality Assurance
Semler Research Center Pvt. Ltd.
P A Arcade, No 21, 22, 23, Kodigehalli Main Road
Sahakarnagar, Bangalore, 560092 India

Dear Lalitha Kamath,

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your premises, **Semler Research Center Private Limited, 75 A, 15th Cross, I Phase, J.P. Nagar, Bangalore, India (Analytical Inspection) & Semler Research Center Pvt. Ltd. PA Arcade, No. 21, 22, 23 Kodigehalli Main Road, Sahakarnagar, Bangalore India (Clinical Inspection)** by the United States Food and Drug Administration (FDA) from **December 9 – 13, 2013.**

The Agency has concluded that this inspection is closed under 21 CFR 20.64(d)(3). We are therefore releasing a copy of the EIR for the inspected establishment to you. The EIR being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and Title 21, Code of Federal Regulations, part 20. However, this does not preclude you from requesting, and possibly obtaining, any additional information provided under FOIA.

The documents provided to you under FDA's FMD-145 Program have not been reviewed for public disclosure, and may contain confidential commercial information (e.g., applicant protocol information) and/or patient information (e.g., patient initials) that you already know in your capacity. FDA would normally redact this type of information before allowing the EIR's public disclosure. **If you were to disclose this information to others, you would be responsible for ensuring that sensitive information is adequately protected.**

If you would like a copy of the EIR that has been reviewed by FDA and redacted for public disclosure, you will need to submit a FOIA request specifically asking for a publicly disclosable version.

If you have any questions about the released information, please contact me by letter at the address given below.

Sincerely,

William H Taylor

William H, Taylor, Ph.D
Director, Division of BEGLPC
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Building 51, Room 5364
10903 New Hampshire Avenue
Silver Spring, MD 20993

Enclosure: Establishment Inspection Report (narrative portion only)