DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

INFORMATION REQUEST

Applicant name
Attention: Point of contact
Address
City, State, Zip Code

Dear Applicant:

During a recent inspection of Semler Research Center Private Limited (SRC), Food and Drug Administration (FDA) investigators issued a Form FDA-483 conveying multiple objectionable findings. Upon consideration of the Office of Study Integrity and Surveillance's inspection assessment, and submissions received from SRC, FDA has concluded that SRC did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of bioequivalence studies. FDA's inspection of the SRC site showed that the company documented practices and processes that undermine the analytical methods used at the SRC site, which resulted in the submission of invalid study data to the FDA. As a result, FDA has significant concerns about the validity and reliability of bioequivalence and bioavailability data generated at SRC that was submitted to the FDA in support of abbreviated new drug applications (ANDAs) and new drug applications (NDAs). FDA issued an "Untitled Letter" to SRC on April 19, 2016, that reflects these conclusions and provides additional detail, see: http://www.fda.gov/Drugs/DrugSafety/ucm495778.htm.

FDA concludes that the integrity and accuracy of data generated at SRC, including the data generated by SRC that you submitted in this application, cannot be assured. Therefore, FDA will not accept data generated at SRC as a basis to approve your application. You must therefore re-conduct those (bioequivalence/bioavailability) studies (both bioanalytical and clinical) at an alternate contract research organization.

Please respond to this letter within 30 days with an amendment to your application. The amendment should describe your plans to address this deficiency.

Sincerely,

U.S. Food and Drug Administration