INFORMATION REQUEST

Applicant Name
Attention: Point of Contact
Address
City, State, Zip Code

Dear Applicant:

Your application contains bioequivalence data generated at Synchron Research Services Pvt. Ltd. (Synchron). The Food and Drug Administration (FDA or the Agency) recently concluded that Synchron did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of bioequivalence studies. The manner in which Synchron conducted multiple studies causes FDA to believe that the reliability and validity of study data generated by Synchron cannot be assured. As a result, FDA has significant concerns about the validity and reliability of bioequivalence and bioavailability data generated at Synchron that was submitted to the FDA in support of abbreviated new drug applications and new drug applications. FDA issued an "Untitled Letter" to Synchron on September 15, 2021 that reflects these conclusions and provides additional detail, see: fda.gov/media/151570/download.

FDA concludes that the integrity and accuracy of data generated at Synchron, including the data generated by Synchron that you submitted in this application, cannot be assured. Therefore, FDA will not accept data generated at Synchron as a basis to approve your application. You must therefore re-conduct those bioequivalence studies (both bioanalytical and clinical portions) at an alternate contract research organization (CRO) (i.e., a CRO other than Synchron, or any other CRO for which FDA has publicly identified unresolved data integrity concerns).

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov