U.S. FOOD & DRUG ADMINISTRATION

INFORMATION REQUEST

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

Dear Applicant:

Your ANDA contains bioequivalence data generated at Synapse Labs Pvt. Ltd. (Synapse). The Food and Drug Administration (FDA or the Agency) recently concluded that Synapse did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of bioequivalence studies. The manner in which Synapse conducted multiple studies causes FDA to believe that the reliability and validity of study data generated by Synapse cannot be assured. As a result, FDA has significant concerns about the validity and reliability of bioequivalence and bioavailability data generated at Synapse that was submitted to the FDA in support of ANDAs and new drug applications. FDA issued a General Correspondence Letter to Synapse on June 17, 2024, that reflects these conclusions and provides additional detail, see: https://www.fda.gov/media/179326/download.

The Office of Generic Drugs (OGD) concludes that the integrity and accuracy of data generated at Synapse, including the data generated by Synapse that you submitted in this application, cannot be assured. Therefore, the data generated at Synapse included in your ANDA is not sufficient to support a bioequivalence finding. You must therefore re-conduct those bioequivalence studies (both bioanalytical and clinical portions) at an alternate study site (i.e., a research organization other than Synapse and other than any study site for which FDA has publicly identified unresolved data integrity concerns).

Please respond to this letter within 30 days with a general correspondence to your application. The general correspondence 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