NDA XXXXXX

INFORMATION REQUEST

APPLICANT NAME
Attention: CONTACT NAME
TITLE
ADDRESS

Dear CONTACT:

Please refer to your new drug application (NDA) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for PROPRIETARY NAME (ESTABLISHED NAME) DOSAGE FORM.

The Food and Drug Administration (FDA or the Agency) recently concluded that Synapse Labs Pvt. Ltd. (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 abbreviated new drug applications and NDAs, including yours. FDA issued a General Correspondence Letter to Synapse on June 17, 2024, that reflects these conclusions and provides additional detail, see: [website URL].

FDA 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, FDA has determined that the data generated at Synapse included in your application are inadequate to support continued approval of your application. You must therefore re-conduct those studies (both bioanalytical and clinical portions) at an alternate study site (i.e., a research organization other than Synapse or any other study site for which FDA has publicly identified unresolved data integrity concerns).

Please respond to this letter within 30 days with a submission to your application. The submission should describe your plans to address this deficiency (e.g., a commitment to re-conduct the studies and a proposed date for timely submission of the study report), or you may request withdrawal of approval of your application. If your submission is not received within 30 days, FDA may initiate proceedings to withdraw the approval of your NDA.

If you have any questions, call XXXXX, Regulatory Project Manager, at NUMBER.

Sincerely,

{See appended electronic signature page}

DIVISION DIRECTOR OR DEPUTY
SIGNATURE BLOCK
TITLE
Division of XXXX
Office of XXXXX
Office of New Drugs
Center for Drug Evaluation and Research