U.S. FOOD & DRUG ADMINISTRATION

INFORMATION REQUEST

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

Dear Applicant:

Your ANDA contains in vitro data generated at Raptim Research, Ltd. (Raptim). FDA has recently concluded that Raptim's failure to acknowledge, identify, and address evidence of in vitro data falsification identified by FDA for multiple subjects/samples across multiple studies creates a risk any products relying on such data are not bioequivalent. Absent a demonstration of bioequivalence, FDA cannot conclude that such products can be expected to have the same clinical effect and safety profile as their respective reference listed drugs when administered to patients under the conditions specified in the labeling. Because Raptim has been responsible for the creation of false in vitro study data in the scope and manner noted above, we have no reason to believe that any in vitro data that Raptim has produced are reliable. Therefore, FDA has determined that all study data from all in vitro studies conducted at Raptim must be rejected. FDA issued an Untitled Letter to Raptim on March 27, 2025, that reflects these conclusions and provides additional detail, see: https://www.fda.gov/media/185841/download.

Accordingly, the Office of Generic Drugs (OGD) concludes that the integrity and accuracy of the data generated by Raptim that you submitted in this application cannot be assured. Therefore, the data generated at Raptim included in your ANDA is not sufficient to support a bioequivalence finding. You must therefore re-conduct those in vitro studies at an alternate study site (i.e., a research organization other than Raptim 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