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Sun Pharma Advanced Research Company (SPARC) announced receipt of a complete response letter from the U.S. Food and Drug Administration (FDA) on its New Drug Application (NDA) for Levetiracetam Extended-release Tablets, 1000mg and 1500mg, an anti-epileptic product. A Complete Response Letter is a communication from the FDA to companies that an NDA cannot be approved in its present form.

In the Complete Response Letter, the FDA specified that the clinical data submitted by SPARC establishes bioequivalence in the fasted state. However, the FDA has raised certain queries on the Pharmacokinetic data in the fed state. SPARC is evaluating the contents of the letter and plans further discussions with the FDA.

Sun Pharma Advanced Research Company is an international pharmaceutical company engaged in research and development of drugs and delivery systems.