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Korean company files suit against DRL

fe Bureau

Hyderabad, Jan 25: Korean biotech company Mezzion Pharma has filed a suit for damages against Dr Reddy's in New Jersey State court alleging that it hid significant deficiencies in its Food and Drug Administration (FDA) cGMP practices and misrepresented its compliance. In a statement, the company said that Dr Reddy's repeatedly represented to Mezzion that it was compliant with FDA regulations and that it hid its misconduct from Mezzion. The suit also states that Dr Reddy's misconduct was the sole reason given by the FDA to deny approval of Mezzion's new drug application (NDA) for udenafil for the treatment of erectile dysfunction (ED) and for FDA's refusal to grant marketing approval of Mezzion's udenafil finished drug product.

As a result, Mezzion has incurred delay and expense and was forced to seek new manufacturers and suppliers for udenafil and the udenafil finished product, and Mezzion is currently taking the necessary steps required to resubmit its udenafil NDA to the FDA for approval.

When contacted, Dr Reddy's spokesperson said, "We are yet to receive any official intimation. Hence, we do not wish to comment on the basis of media reports."

In the suit filed with the New Jersey Court, Mezzion seeks to recover from Dr Reddy's millions of dollars in damages for fraud, fraudulent concealment and other counts.