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Dr Reddy's re-launches Buprenorphine, Naloxone Sublingual Film

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The re-launch comes on the heels of a favorable decision issued by the United States Court of Appeals for the Federal Circuit.

Dr. Reddy's Laboratories Ltd. has announced the re-launch of its Buprenorphine and Naloxone Sublingual Film, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, a therapeutic equivalent generic version of Suboxone® (buprenorphine and naloxone) sublingual film, in the United States market.

The re-launch comes on the heels of a favorable decision issued by the United States Court of Appeals for the Federal Circuit concluding that Indivior had not shown that it is likely to succeed on its claim that Dr. Reddy's product infringes U.S. Patent No. 9,931,305. The Federal Circuit's decision vacates the District Court's preliminary injunction that had prohibited Dr. Reddy's from selling its generic version of Suboxone® (buprenorphine and naloxone) sublingual film. The Federal Circuit's decision went into effective yesterday. As a result of the Federal Circuit's ruling, Dr. Reddy's has resumed shipping of the product.

"We are pleased with the decision of the appellate court in Dr. Reddy's favor, vacating the preliminary injunction that had prevented Dr. Reddy's from continuing to market this important drug to the public," explains Marc Kikuchi, Chief Executive Officer, North America Generics. "Dr. Reddy's is committed to providing affordable treatment options for opioid use disorder and addiction. We look forward to helping patients and our communities in the United States who are impacted by the opioid epidemic."

In June 2018, the U.S. Food and Drug Administration (USFDA) approved Dr. Reddy's Buprenorphine and Naloxone Sublingual Film, in four strengths including 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, for sale in the U.S. market. The product was launched immediately after approval, with sales and commercialization activities halted as a result of a court-imposed temporary restraining order (TRO) and preliminary injunction against Dr. Reddy's. The TRO and preliminary injunction did not prohibit commercial manufacturing of the product.