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Actavis files ANDA for Reckitt generic with FDA

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Singapore: Actavis has filed an abbreviated new drug application (ANDA) with the US FDA seeking approval to market Buprenorphine Hydrochloride and Naloxone Hydrochloride Sublingual Film 2 mg/0.5 mg and 8 mg/2 mg.

Actavis' ANDA product is a generic version of Reckitt Benckiser's Suboxone Sublingual Film, which is indicated for maintenance treatment of opioid dependence.

Reckitt Benckiser Pharmaceuticals, RB Pharmaceuticals Limited and MonoSol Rx filed suit against Actavis on October 8, 2013, in the US District Court for the District of Delaware seeking to prevent Actavis from commercializing its ANDA product prior to the expiration certain of US patents.

The lawsuit was filed under the provisions of the Hatch-Waxman Act, resulting in a stay of final FDA approval of Actavis' ANDA for up to 30 months from the date the plaintiffs received notice of Actavis' ANDA filing or until final resolution of the matter before the court, whichever occurs sooner, subject to any other exclusivities.

Based on available information, including a submission date listed on FDA's Paragraph IV Patent Certifications web site that is consistent with the date of Actavis' ANDA filing, Actavis believes it may be a 'first applicant' to file an ANDA for a generic version of Suboxone Film and, should its ANDA be approved, may be entitled to 180 days of generic market exclusivity.

For the 12 months ending August 31, 2013, Suboxone Film 2/0.5mg and 8/2 mg reported total US sales of approximately $1.2 billion, according to IMS Health data.