

Mylan files ANDA for MS drug

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Mylan, the US-based global generic drug maker has filled a ANDA with the regulatory body for its drug, Copaxone.

"Our marketing partner in the USA, Mylan has filed an abbreviated new drug application (ANDA) for a three-times-a-week generic Copaxone (glatiramer acetate injection) and has been accepted by the US Food and Drug Administration (US FDA)," said Natco pharma, partner of Mylan in a filling.

The ANDA is for the product in the strength of 40 mg/mL, it added.

"Mylan believes it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for this product and expects to be eligible for 180 days of market exclusivity in the US upon final FDA approval," said the company.

According to IMS health, Copaxone 40 mg/mL had US sales \$411.5 million till June 2014.