



Natco Pharma Limited

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NATCO confirms filing of ANDA for Generic Revlimid®

Hyderabad based **NATCO** Pharma Limited today confirmed that the company has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) seeking approval to market lenalidomide capsules in 5, 10, 15 and 25mg strengths prior to the expiration of various U.S. patents. **NATCO's** lenalidomide capsules are the generic version of Celgene Corporation's Revlimid®.

On August 30, 2010, pursuant to the Hatch-Waxman Act, **NATCO** notified Celgene that its ANDA requesting approval from the FDA for a generic version of Revlimid® contained a paragraph IV certification asserting that various Revlimid® patents are invalid, unenforceable and/or not infringed. Lenalidomide, which is presently marketed as **Revlimid** by Celgene, is a derivative of thalidomide and is used in the treatment for multiple myeloma. Lenalidomide has also shown efficacy in the class of hematological disorders known as myelodysplastic syndromes (MDS).

NATCO believes it may be a "first applicant" to file an ANDA for the 25 mg generic version of Revlimid® and, should its ANDA be approved, may be entitled to 180 days of generic market exclusivity for that strength.

The market size of Revlimid in the USA is estimated to be around US \$ 1.5 Billion, growing at 44% compared to last year.

Forwarded for favor of publication

For NATCO PHARMA LIMITED

M. ADINARAYANA
Company Secretary & G.M.
(Corporate Affairs)