

NATCO receives final approval for generic TAMIFLU

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<u>Natco Pharma</u> Limited has received final approval of Abbreviated New Drug Application (ANDA) containing a paragraph IV certification filed with the US Food and Drug Administration (FDA) for generic versions of TAMIFLU oral capsules (Roche's trade name for Oseltamivir Phosphate), 30 mg, 45 mg and 75 mg.

Also read: Sanofi receives FDA approval for Adlyxin

Earlier in December, 2015, NATCO and Alvogen settled a patent infringement with Gilead Sciences, Inc., Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Genentech, Inc.

Under the terms of the settlement, NATCO's partner Alvogen will be able to market the oseltamivir phosphate capsules before the expiration of the pediatric exclusivity period listed in FDA's Orange Book for U.S. Patent No. 5,763,483, which is February 23, 2017.

TAMIFLU oral capsules had U.S. sales of approximately \$403 Million for twelve months ending December 2015, according to IMS Health.