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Actavis 'pregnancy preventer' gets FDA nod

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Singapore: US FDA has accepted Actavis' New Drug Application (NDA) for a progestin-only transdermal contraceptive patch (Norethindrone Transdermal Delivery System) for use by women to prevent pregnancy.

The acceptance of the NDA for filing means FDA has determined that the application is sufficiently complete to permit a substantive review. The acceptance for filing does not provide any assurance that the FDA will ultimately approve the NDA.

Under the Prescription Drug User Fee Act (PDUFA), the FDA's goal under standard review is to review and act on the NDA by December 27, 2013.

Actavis' progestin-only patch is designed to provide continuous delivery of norethindrone to the systemic circulation during a once-weekly, seven-day dosing regimen. Once-weekly dosing with the patch may improve compliance and convenience in progestin-only contraceptive users, as well as provide more consistent average plasma norethindrone levels than oral progestin-only products.

The NDA includes data from a 12-month, multicenter, open-label clinical trial conducted in the US, in accordance with FDA guidance for a contraceptive study. Actavis submitted the NDA to the FDA on February 26, 2013.