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US FDA extends timeline for generic drug approval

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Singapore: In a recent move, the US Food and Drug Administration (FDA) has decided to extend the timeline for granting tentative approval to generic drug applications. The timelines of applications filed under Paragraph IV have been increased from 30 months to 40 months for those whose 30-month stay expires between July 9, 2012, and September 30, 2015, and 30 months to 36 months for those whose 30-month stay expires between October 1, 2015, and September 30, 2016.

It is expected that this period would be gradually phased back down to 30 months after the FDA addresses the backlog of ANDA filings estimated at 2,500 at present.

When a company files a paragraph IV generic application in the US and if the application is challenged by the innovator, the court gives a stay on the product for 30 months. The generic company, however, can launch the product if the court rules in its favor. The company can also launch the product after this 30-month period is over if it gets approval from the FDA. However, the company has to get a tentative approval from the FDA within 30 months of the filing the application if it wants to retain the 180 days exclusive marketing rights on the product. This 30 months period has now been extended to 40 months.

This move can delay the launch of generic drugs in the market. Even if the company wins the case in the US courts against the innovator company, they will not be able to launch the product if it is not approved by the agency. On the contrary, some drug makers can benefit from the extension of the time frame.