

## FDA's call on Rytary delayed by 3 months

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**Singapore:** Impax laboratories in Taiwan recently announced that FDA had delayed its decision on Rytary, the first non-generic drug developed for Parkinson's disease by three months, to January 9, 2015.

Impax had made changes to its new drug application to the FDA for Rytary and major amendments to an application within three months of an FDA decision date can give a company a 90-day extension, said reports.

Ms Shibani Malhotra, an analyst at brokerage firm Sterne Agee said the extension will provide Impax more time to work on manufacturing issues at the facility. Earlier an FDA inspection at the company's Taiwan facility found, among other things, the use of invalidated manufacturing equipment and failure to conduct a thorough review of failed drug batches.