BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Finally, Impax's Parkinson's drug gets FDA approval

January 12, 2015 | News | By BioSpectrum Bureau

USFDA nods for Impax's Rytary



Singapore: After years of rejecting approval for Impax's flagship drug Rytary, a treatment for Parkinson's disease, the USFDA has finally given its nod. Rytary is a formulation of carbidopa-levodopa, the standard care for Parkinson's disease, which is characterized by reduced dopamine levels in the brain.

The approval was delayed due to compliance issues cited by the FDA at the drugmaker's manufacturing facilities. The FDA had also issued a warning letter to Impax, following which, the company had announced a series of leadership changes and also severe staff cuts.

The FDA's rejection cost Impax its partnership with GlaxosmithKline, which terminated its agreement to market the drug outside United States and Taiwan. The company is said to have resolved the manufacturing issues and submitted the application for reconsideration.

The market for Parkinson's therapies booming, and an estimated one million Americans are currently living with Parkinson's disease. A full commercial launch will not occur until April, according to the investment banking firm Sterne Agee.