URGENT

PRESS RELEASE

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Wockhardt receives US FDA approval for the generic version of Allegra-D® 12 hour

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Pharmaceutical and biotechnology major Wockhardt has received tentative approval from the United States Food & Drug Administration (US FDA) for marketing the Fexofenadine HCl 60mg + Pseudoephedrine HCL 120mg extended release tablets which is used for treatment of seasonal allergic rhinitis without causing drowsiness. Fexofenadine plus Pseudoephedrine is the generic name for the brand Allegra-D® 12 hour, marketed in the United States by Sanofi Aventis. The patent covering this product is under litigation in the US courts and Wockhardt will launch the product after resolution of the same.

"Wockhardt is amongst only four companies to have received US FDA approval for this drug which is the most prescribed antihistamine plus decongestant product", said Wockhardt Chairman Habil Khorakiwala. "This is yet another extended release product from the R&D pipeline of Wockhardt and the fourth such product to be approved by the US FDA in the year", he further added.

According to Wolters Kluwer, the total market for this product in the US is about $214 million and belongs to the class of non-sedating antihistamines. The product is an extended release bi-layered tablet and requires specialised technology and manufacturing capability.

In the US generic pharmaceutical market, Wockhardt has been consistently growing market shares for all its products. In many instances, Wockhardt, by virtue of being amongst the first to market, has reaped the advantage of being an early entrant.

The tablets will be manufactured at the US FDA certified formulation plant at Waluj, Aurangabad and the Fexofenadine HCl API will be manufactured in the FDA certified API plant at Ankleshwar, Gujarat. The tablets and the API were developed in-house.

About Wockhardt

Wockhardt is a technology-driven global pharmaceutical and biotechnology major with an innovative multi-disciplinary research and development programme. It has 5 research centres and 14 world-class manufacturing plants dotting various countries and continents that are compliant to international regulatory standards such as the US FDA, MHRA and other global regulatory bodies. It has end-to-end integrated capabilities for its products, starting with manufacture of the oral and sterile API's, the dosage forms and marketing through its wholly owned subsidiary in the US. Wockhardt has a global footprint including the US, UK, Ireland and France with a multi-ethnic workforce from 14 different nationalities.