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Lupin's sNDA Antara Capsules receive FDA nod

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Singapore: Indian drug major Lupin Limited's New Drug Application Antara capsules have received the US drug regulator's approval.

The US Food and Drug Administration (FDA) provided its final approval for the company's supplemental New Drug Application (sNDA) Antara (Fenofibrate) capsules, 30 mg and 90 mg strengths.

Lupin's US subsidiary will begin marketing the product soon while the new drug would be manufactured by Lupin.

Antara capsules are prescribed for adjunct treatment of hypercholesterolemia (high blood cholesterol), mixed dyslipidemia and hyper-triglyceridemia (high triglycerides) in combination with diet.

"We are very pleased to receive this approval. The approval demonstrates Lupin's commitment to building its brand franchise in the US. Our sales and marketing efforts will commence shortly," Ms Vinita Gupta, Chief Executive Officer, Lupin Limited said in a statement.

As per IMS Health reports, Lupin is the fifth largest and fastest growing top five generics player in the US with 5.3 percent market share by prescriptions. The company is also the third largest Indian pharmaceutical company by sales

For the financial year ended March 2013, Lupin's Consolidated turnover and Profit after Tax were $ 1.74 billion (Rs 94,616 million) and $ 242 million (Rs 13,142 million) respectively.