Glenmark secures FDA final approval for its heartburn capsules

Glenmark has received ANDA approval for its Esomeprazole Magnesium Delayed-Release Capsules. The regulator has determined the drugs as bioequivalent1 to Nexium 24 HR Delayed-Release Capsules which according to an estimate has an annual sale of $259.2 million.

Mahwah: Glenmark Specialty SA (Glenmark) has received final approval from the United States Food and Drug Administration (USFDA) for its Esomeprazole Magnesium delayed-release capsules USP, 20 mg (OTC), which are used to Abbreviated New Drug Application (ANDA) heartburns.

The regulator has determined the capsules as bioequivalent1 to Nexium 24 HR delayed-release capsules, 20 mg (OTC), of Haleon U.S. Holdings LLC. Esomeprazole

Having secured the ANDA approval, the drugs seems to have a positive outlook

With the ANDA approval in hand, the drug is poised to enter the US market and can make its space in the expanding market. According to Nielsen syndicated data for the latest 52 weeks period ending May 18, 2024, the Nexium 24 HR delayed-release capsules, 20 mg (OTC) market3 achieved annual sales of approximately $259.2 million.

Glenmark's current portfolio consists of 197 products authorized for distribution in the US marketplace, while apart from this, currently the drug-maker has 50 ANDA's pending approval with the USFDA.

News Source:

https://health.economictimes.indiatimes.com/news/pharma/drug-approvals-launches/glenmark-secures-fda-final-approval-for-its-heartburn-capsules/110931484