Zydus Lifesciences gets USFDA nod to produce prostrate cancer drug

Zydus Lifesciences has received tentative approval from the US Food and Drug Administration (USFDA) to manufacture Enzalutamide tablets (40 mg and 80 mg), the drug maker said in a regulatory filing.

Zydus Lifesciences on Wednesday said it has received approval from the US health regulator to produce a generic prostate cancer treatment drug.

The company has received tentative approval from the US Food and Drug Administration (USFDA) to manufacture Enzalutamide tablets (40 mg and 80 mg), the drug maker said in a regulatory filing.

Enzalutamide tablets are androgen receptor inhibitors indicated for the treatment of patients with castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer.

The product would be manufactured at the Group's manufacturing site at SEZ, Ahmedabad.

As per IQVIA MAT July 2024 data, Enzalutamide tablets (40 mg and 80 mg) had annual sales of $1,417.2 million in the US.

The Zydus group now has 400 approvals and has so far filed over 465 Abbreviated New Drug Application (ANDAs) since the commencement of the filing process in FY 2003-04, it said.

News Source:

https://www.cnbctv18.com/market/zydus-lifesciences-gets-usfda-nod-to-produce-prostrate-cancer-drug-19486188.htm