Zydus receives Tentative Approval from the USFDA for Dexamethasone Tablets USP, 1 mg

Ahmedabad, India, February 09, 2024

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as "Zydus") has received tentative approval from the United States Food and Drug Administration (USFDA) to manufacture and market Dexamethasone Tablets USP, 1 mg (USRLD: Dexamethasone Tablets).

Dexamethasone is used to treat conditions such as arthritis, blood/hormone disorders, allergic reactions, skin diseases, eye problems, breathing problems, bowel disorders, cancer, and immune system disorders. The product will be manufactured at the group's formulation manufacturing facility at Baddi, Himachal Pradesh.

Dexamethasone Tablets USP, 1 mg had annual sales of USD 1.8 mn in the United States (IQVIA Dec. Nov. 2023).

The group now has 387 approvals and has so far filed over 460* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2023)

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PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)
Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878