Zydus Cadila's Sitagliptin base tablets receives Tentative Approval from FDA

September 6, 2021, Ahmedabad India

Zydus Cadila today announced that its subsidiary has received tentative approval from the United States Food and Drug Administration (FDA) for its new drug application for Sitagliptin base 25, 50 and 100 mg tablets. Zydus' Sitagliptin base contains the active moiety Sitagliptin in a different form than used in the branded reference product, Januvia® (Sitagliptin Phosphate).

On October 31, 2020, Zydus filed a New Drug Application (NDA) under Section 505(b)(2) of the Federal Food and Drug Cosmetic Act (FD&C Act) with the United States Food and Drug Administration (FDA) seeking approval to market Sitagliptin base 25, 50 and 100 mg tablets. Zydus' NDA received tentative approval upon completion of the first review cycle on September 2, 2021.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures, and markets a broad range of healthcare therapies including small molecule drugs, biologic therapeutics, and vaccines. The group employs 23000 people worldwide and is dedicated to creating healthier communities globally. For more information, please visit www.zyduscadila.com/

Januvia® is a registered trademark of the Merck.

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