

Zydus to supply Sagent's Caffeine Citrate Oral Solution from Jarod, post USFDA's PAS Approval

Ahmedabad, April 13, 2022

Zydus Lifesciences's (Formerly known as Cadila Healthcare Ltd.), an innovation-led global lifesciences company announced that it will be manufacturing and supplying Sagent's Caffeine Citrate Oral Solution in the strength of 60 mg per 3 mL (20 mg per mL) Single-dose Vial (US RLD: CAFKIT) from its injectables facility at Jarod, Gujarat, India. The company announced that it received the Prior Approval Supplement (PAS) Approval from the US Food and Drug Administration (USFDA), which allows for a site transfer and manufacturing of the drug at Jarod.

This product is indicated for the short-term treatment of a breathing problem (Apnea) in premature infants. Caffeine blocks certain proteins (adenosine receptors) which leads to improved breathing in these infants.

Sagent Pharmaceuticals, Inc. (Sagent), a Nichi-Iko Group Company, is a specialty pharmaceutical company focused on developing, manufacturing, sourcing, and marketing pharmaceutical products for the North American market, with a specific emphasis on injectables.

Prior Approval Supplement (PAS)

A Prior Approval Supplement (PAS) is an application which seeks to make changes to an already approved application, such as an Abbreviated New Drug Application (ANDA), which is used by the USFDA to approve generic drugs.

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 23000 people worldwide and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking discoveries. For more details visit www.zyduslife.com.

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