

USFDA classifies Strides Puducherry facility as Official Action Initiated (OAI)

06 May 2019 | News

Strides Pharma Science Ltd said that the US health regulator has classified its Puducherry facility as official action initiated (OAI) for non-compliance of norms following an inspection



Strides Pharma Science Ltd. has received a communication from the US Food and Drug Administration (USFDA) on May 4, 2019, classifying the facility as OAI based on the inspection conducted from January 28 to February 5, 2019.

According to the USFDA, an OAI means regulatory and/or administrative actions will be recommended for the facility which was inspected after it determines if the areas evaluated were in compliance with applicable laws and regulations.

"While the company is disappointed with the outcome of the inspection, the company believes that the classification will not have an impact on the current supplies and revenues from the facility," Strides Pharma Sciences said in statement.

However, of the 34 ANDA's pending approval, Puducherry has 10 ANDA's where the Company expects delays until the facility is reclassified.