BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Strides Pharma receives USFDA nod for two key ANDAs

22 August 2018 | News

The USFDA also granted Strides' request to designate the drug product under these ANDAs as a Competitive Generic Therapy (CGT)

India's Strides Pharma has announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, received ANDA "acceptable for filing" correspondence from the USFDA for two key ANDAs that met the prioritization factors as a potential First Generic with a 10- month GDUFA II review goal date.

As per IQVIA MAT data, the US market for these products cumulatively is US$ 550 Mn. The USFDA also granted Strides' request to designate the drug product under these ANDAs as a Competitive Generic Therapy (CGT).

If Strides is the first approved applicant with such competitive generic therapies, these products could be eligible for a potential 180-day CGT exclusivity, which functions in a similar manner to the Patent Challenge exclusivity for ANDAs.

Approval of the CGT designated ANDAs will be contingent on certain conditions including continued USFDA approval status for the manufacturing plant, API supplier, and CRO. While the CGT designated ANDAs will be eligible for a 180-day CGT exclusivity as subsequent generic will not be approved to market for 180 days after launch, the exclusivity will not preclude the marketing of product that receives approval prior to Strides commercializing the product.

A drug is eligible for designation as a competitive generic therapy if FDA determines that there is "inadequate generic competition". Inadequate generic competition means there is not more than one approved drug listed in the Orange Book

(excluding discontinued section) that is the RLD, or a generic drug with the same RLD as the drug for which designation as a competitive generic therapy is sought.

The CGT designation benefits include involvement of senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review of a CGT designated ANDA. The product could also be eligible for potential 180-day CGT exclusivity if the application is for a drug, which is considered the “first approved applicant” with such competitive generic therapies.