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Dr Reddy's gets FDA nod for generic Revlimid; enjoys 180 days exclusivity

Synopsis
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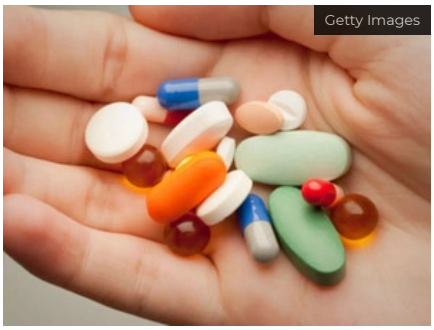

(Representational image)

Dr. Reddy's Laboratories Ltd. on Tuesday announced the final approval of its Abbreviated New Drug Application (ANDA) for **Lenalidomide capsules**, from the U.S. Food and Drug Administration (**USFDA**).

According to a press release issued by the Hyderabad-based drug maker, the FDA approved Lenalidomide capsules in 2.5 mg and 20 mg strengths, and gave tentative approval for 5 mg, 10 mg, 15 mg, and 25 mg strengths. Lenalidomide is used to treat various types of cancers. With this approval, Dr. Reddy's is eligible for 180 days of generic drug exclusivity for Lenalidomide capsules, 2.5 mg and 20 mg, it said.

In September 2020, Dr. Reddy's announced a settlement agreement of their litigation with Celgene, the maker of **Revlimid** (lenalidomide) capsules and a wholly-owned subsidiary of Bristol Myers Squibb relating to patents for the branded drug.

"We are pleased with the Agency's approval of Lenalidomide Capsules, 2.5 mg and 20 mg and being eligible for 180-day market exclusivity. We look forward to bringing a more affordable generic version of this drug to market for the benefit of patients," Marc Kikuchi, CEO, North America Generics, Dr. Reddy's Laboratories said.

In settlement of all outstanding claims in the litigation, Celgene agreed to provide Dr. Reddy's with a license to sell volume-limited amounts of generic lenalidomide capsules in the U.S. beginning on a confidential date after March 2022 subject to regulatory approval.

The agreed-upon percentages remain confidential. As part of the settlement, Dr. Reddy's is also licensed to sell generic lenalidomide capsules in the U.S. without volume limitation beginning January 31, 2026, the release said.

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