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Dr Reddy's Labs bags US FDA approval for Lenalidomide caps

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Dr Reddy's is eligible for 180 days of generic drug exclusivity for Lenalidomide capsules, 2.5 mg and 20 mg

Dr Reddy's Laboratories announced the final approval of its Abbreviated New Drug Application (ANDA) for Lenalidomide Capsules, in 2.5 mg and 20 mg strengths, and tentative approval for 5 mg, 10 mg, 15 mg, and 25 mg strengths, a therapeutic equivalent generic version of REVLIMID (lenalidomide) Capsules, from the US Food and Drug Administration (USFDA). With this approval, Dr Reddy's is eligible for 180 days of generic drug exclusivity for Lenalidomide capsules, 2.5 mg and 20 mg.

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.

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 US 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 US without volume limitation beginning on January 31, 2026.

"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," says Marc Kikuchi, CEO, North America Generics, Dr Reddy's Laboratories.