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Granules receives USFDA approval for complex ADHD drug

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The generic equivalent of Focalin™ XR will make Granules a strong player in the $556 M US market

Hyderabad based Granules, a world-leading APIs & formulations corporation recently announced its US subsidiary has received marketing approval from the U.S. Health Regulator (FDA) for Dexmethylphenidate HCl extended-release capsules for the treatment of attention-deficit hyperactivity disorder. Granules' capsule product is bioequivalent to the reference listed drug (RLD), Focalin™ XR.

Priyanka Chigurupati, Executive Director of Granules Pharmaceuticals Inc. said "This approval for Granules Pharmaceuticals Inc, received within 13 months of filing reiterates our strength in the development of complex generics. The approval of Dexmethylphenidate XR, a complex, extended-release C-II product, is a good addition to our portfolio. We will be launching the product in the US market soon."

The drug will be manufactured at the Granules manufacturing facility in Chantilly, Virginia. Granules now have a total of 30 ANDA approvals from the US FDA (28 Final approvals and 2 tentative approvals).

According to IQVIA Health, Dexmethylphenidate HCl ER Capsules had U.S. sales of approximately $556 million for the most recent twelve months ending in July 2020.

Focalin™ XR is a trademark of Novartis AG.