Lupin gets FDA nod for UCD drug

Glycerol phenylbutyrate is indicated for chronic management of patients with urea cycle disorders (UCDs) that cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

Mumbai: Lupin Limited announced that it's Abbreviated New Drug Applications (ANDA) for Glycerol Phenylbutyrate has received approval from the United States Food and Drug Administration (FDA).

The approved generic is bioequivalent of Horizon Therapeutics's to Ravicti Oral Liquid and has an estimated market of $337 million in the US.

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News Source:

https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/aurobindo-pharma-arm-curateq-gets-health-canada-nod-for-biosimilar/130742679