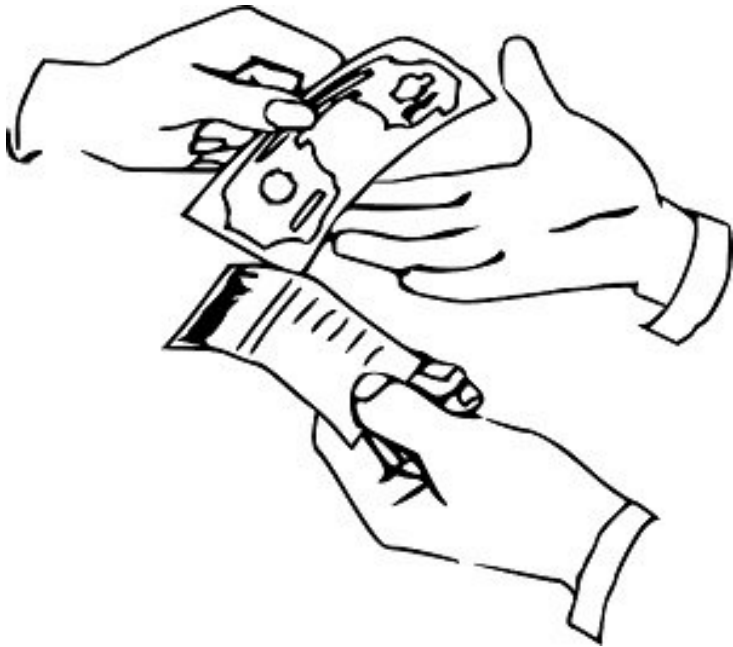


FDA nod for Cipla's new generic

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FDA nod for Cipla's new generic



Cipla Limited has received final approval for its Abbreviated New Drug Application (ANDA) for Darifenacin Extended-Release Tablets, 7.5mg and 15mg, from the United States Food and Drug Administration (USFDA).

Darifenacin Extended-Release Tablets, 7.5mg and 15mg, are AB-rated generic equivalents of Allergan's Enablex Tablets, 7.5mg and 15mg, and are a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency. The product will be launched immediately.

Enablex Tablets and generic equivalents had U.S. sales of approximately \$85M for the 12 month period ending June 2016, according to IMS Health.