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Aurobindo Pharma receives FDA approval for Naproxen Sodium Tablets

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Aurobindo Pharma is pleased to announce that the company has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Naproxen Sodium Tablets USP, 220 mg (OTC). This product is expected to be launched in Q1 FY16-17.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Aleve Tablets, of Bayer Healthcare.

Naproxen Sodium Tablets is used in the treatment and prevention of osteoporosis in postmenopausal women. The approved product has an estimated market size of $96 million for the twelve months ending January 2016 according to IMS.