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Aurobindo receives FDA approval for ulcer drug

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Aurobindo Pharma has announced that the company has received the final approval from the US Food and Drug Administration (US FDA) to manufacture and market Omeprazole Delayed-release Capsules USP, 10mg, 20mg and 40mg (ANDA 203270).

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Prilosec Delayed-release Capsules, 10mg, 20mg and 40mg of AstraZeneca Pharmaceuticals.

Omeprazole Delayed-release Capsules are indicated for short-term treatment of active duodenal ulcer in adults. The product has an estimated market size of $422 million for the twelve months ending June 2015, according to IMS.