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FDA OKs Generic Version of Flonase

Generic Version Is Called Fluticasone
Propionate Nasal Spray

By [Miranda Hitti](#)



FROM THE WEBMD ARCHIVES



Feb. 22, 2006 -- The FDA has approved the first generic version of the brand-name drug [Flonase](#), a nasal spray that treats allergic and nonallergic nasal symptoms.

The generic product is called fluticasone propionate nasal spray. It's approved for use in adults and children who are at least 4 years old.

The generic spray contains a synthetic, inflammation-fighting corticosteroid. Fluticasone propionate, like other corticosteroids, doesn't have an immediate effect on [allergic symptoms](#).

A decrease in nasal symptoms (stiffness,

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after initial treatment. Common side effects of fluticasone propionate nasal spray are [headache](#), [sore throat](#), and nose bleed.

FDA's Comments

"Except for their price, which is much lower, [generic drugs](#) are in every way equivalent to their brand-name counterparts," says Steven Galson, MD, MPH, in an FDA news release. Galson directs the FDA's Center for Drug Evaluation and Research.

"Offering consumers a choice of safe, effective, and reasonably priced generic drug products is an extremely important priority for [the] FDA. Today's approval is part of our ongoing commitment to provide generic forms of products to the public," Galson continues.

Generic drug products are used to fill over 50% of all [prescriptions](#) and cost a fraction of the price of brand-name drugs. In 2005, the FDA approved 452 generic drug applications, the second highest total on record.

Brand-Name Patent Expired

The brand-name version of the spray, Flonase, is manufactured by GlaxoSmithKline. The patent for Flonase expired in May 2004. GSK is a WebMD sponsor.

The FDA received several petitions from citizens questioning the approval criteria for the generic spray, according to an FDA news release. After reviewing those

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"The FDA submits generic drug applications to the same thorough and rigorously scientific review for safety, effectiveness, and quality as the applications for new drugs," the release states.

"Consumers and health professionals can be assured that an approved generic drug is bioequivalent to a brand-name drug and is its equal in dosage form, strength, route of administration, quality, performance characteristics, and intended use," the release continues.

The nasal spray's generic version is made by Roxane Laboratories of Columbus, Ohio.

WebMD Health News | Reviewed by [Louise Chang, MD](#) on February 22, 2006

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