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FDA approves generic of commonly used albuterol inhaler

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The first generic albuterol sulfate (Proventil HFA) metered-dose inhaler, 90 mcg/inhalation has been approved by the Food and Drug Administration (FDA) for patients ages 4 years and older.

The product is indicated for the treatment or prevention of bronchospasm in patients with reversible obstructive airway disease, as well as the prevention of exercise-induced bronchospasm.

There is an increased demand for albuterol products, particularly during the coronavirus disease 2019 pandemic, the FDA noted. In March, the FDA issued a revised draft of product-specific guidance for proposed generic albuterol sulfate metered-dose inhalers.

Manufactured by Cipla Limited, the generic inhaler was granted FDA approval based on data and information demonstrating that it met bioequivalence recommendations and standards ensuring quality to be as safe and effective as the brand-name counterpart.

According to a company statement, product shipments are being planned in a staggered manner, and inhalers also are being donated during the pandemic.