

Cipla Receives U.S. FDA Approval for First AB-Rated Generic of Ventolin® HFA

Mumbai, India and Warren, New Jersey, USA – April 23, 2026: Cipla Limited (BSE: 500087; NSE: CIPLA EQ; and hereafter referred to as "Cipla") and its wholly owned subsidiary Cipla USA Inc., (hereafter referred to as "Cipla"), today announced that it has received final approval for its Abbreviated New Drug Application (ANDA) for Albuterol Sulfate Inhalation Aerosol, 90 mcg per actuation from the United States Food and Drug Administration (USFDA). It is the first AB-rated generic therapeutic equivalent of Ventolin® HFA, marketed by GlaxoSmithKline.

Albuterol Sulfate Inhalation Aerosol is indicated for the treatment or prevention of bronchospasm in adult and pediatric patients aged four years and older with reversible obstructive airway disease, as well as for the prevention of exercise-induced bronchospasm in patients aged four years and older.

According to IQVIA*, the total U.S. albuterol market is valued at approximately \$1.5 billion.

This approval enhances Cipla's U.S. respiratory portfolio and reinforces its leadership in the albuterol inhalation category, with approved generics for both Ventolin® HFA and Proventil® HFA.

Commenting on the approval, **Achin Gupta, Managing Director & Global CEO, Cipla Limited**, said: "This marks an important milestone for Cipla and reflects our strong scientific and regulatory capabilities in complex inhalation products. Lung health remains at the heart of all our offerings and follows a singular, distilled objective, to build a sustainable and differentiated portfolio for patients globally."

The product is backed by Cipla's vertically integrated inhalation platform, reflecting the company's continued investment in U.S.-based manufacturing for complex respiratory therapies.

Marc Falkin, Chief Executive Officer, Cipla North America, added: "Strengthening our U.S. respiratory franchise, the product will be manufactured at our newly constructed, dedicated inhalation facility in Fall River, Massachusetts, reinforcing both supply resilience and our domestic manufacturing footprint. With planned volume ramp-up, we expect to drive meaningful difference in the lives of patients."

About Cipla Limited

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, antiretroviral, urology, cardiology, anti-infective and CNS segments are well-known. Our 46 manufacturing sites around the world produce 50+

dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT Dec'25), 2nd Largest in the pharma prescription market in South Africa (IQVIA MAT Nov'25), and 3rd largest by prescription in the US Gx (Repulses + MDI) products (IQVIA MAT Dec'25). For nine decades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility and affordability to the centre of the HIV movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring for Life' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers and all stakeholders. it a partner of choice to global health bodies, peers and all stakeholders. For more, please visit www.cipla.com, or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

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