



Cipla Receives U.S. FDA Approval for Generic Advair Diskus®

(Fluticasone Propionate and Salmeterol Inhalation Powder), across all three strengths

Mumbai, India and Warren, New Jersey, USA – July xx, 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 Cipla Limited has received U.S. Food and Drug Administration (FDA) approval for its Abbreviated New Drug Application (ANDA) for Generic Advair Diskus® (fluticasone propionate and salmeterol inhalation powder) in all three strengths—100/50 mcg, 250/50 mcg, and 500/50 mcg.

The product is a therapeutically equivalent version of Advair Diskus®, a widely prescribed combination therapy indicated for the treatment of asthma and chronic obstructive pulmonary disease (COPD). According to IQVIA, the U.S. market for fluticasone propionate and salmeterol inhalation powder is approximately \$908 million. This approval represents Cipla's first dry powder inhaler (DPI) approval from its U.S.-based manufacturing network, marking a significant milestone in the company's continued expansion of complex respiratory capabilities in the United States.

Commenting on the approval, **Achin Gupta, Managing Director & Global CEO, Cipla Limited**, said: "At Cipla, we're passionate about respiratory care given our long-standing expertise. This approval reinforces our commitment to expanding access to complex therapies in the U.S. and highlights our strength in developing and scaling sophisticated inhalation products through integrated capabilities."

Backed by Cipla's vertically integrated inhalation platform, the product reflects the company's commitment to strengthening U.S. manufacturing capabilities for complex respiratory treatments.

Marc Falkin, Chief Executive Officer, Cipla North America, added: "This approval marks our first dry powder inhaler from our New York facility and reflects our targeted investments in building differentiated inhalation manufacturing capabilities in the U.S. It strengthens our ability to provide reliable, high-quality supply in an important and competitive category"

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 70+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT Jun'26), 2nd Largest in the pharma prescription market in South Africa (IQVIA MAT May'26), and 2nd largest by prescription in the US Gx (Repulses + MDI) products (IQVIA MAT Jun'26). 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 center 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. For more, please visit www.cipla.com, or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

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