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Cipla receives approval for Albuterol Sulfate Inhalation Aerosol

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It is used for treatment of acute episodes of bronchospasm or prevention of asthmatic symptoms

Cipla has announced the final approval for its Abbreviated New Drug Application (ANDA) for Albuterol Sulfate Inhalation Aerosol 90mcg (base)/actuation, from the United States Food and Drug Administration.

It is the first AB-rated generic therapeutic equivalent version of Merck Sharp & Dohme Corp's Proventil HFA Inhalation Aerosol and is used for treatment of acute episodes of bronchospasm or prevention of asthmatic symptoms.

Umang Vohra, MD and Global CEO, Cipla Limited said, "We are pleased to receive the final approval for generic Albuterol MDI from the USFDA. This further strengthens our presence in the US market. Albuterol is the first generic metered dose inhaler of Proventil HFA Inhalation Aerosol ever approved by FDA in the US and Cipla's first device-based inhalation product in the market. This development reiterates our commitment of strengthening our respiratory franchise and will further solidify our position as lung leader globally. We will continue to build on our portfolio of drug-device combinations in the respiratory space to serve the unmet needs of our patients across markets."

According to IQVIA (IMS Health), Proventil HFA Inhalation Aerosol and its authorized generic equivalent had US sales of approximately $153M for the 12-month period ending February 2020. The entire Albuterol Sulfate HFA Inhalation Aerosol market had US sales of approximately $2.8 Billion for the 12-month period ending February 2020.