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July 11, 2007

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration 21 CFR Part 2
[Docket No. 2006N-0454] RIN 0910-AF93
Use of Ozone-Depleting Substances; Removal of Essential-Use Designations

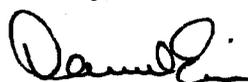
Dear Colleague:

The American College of Allergy, Asthma, and Immunology representing over 2500 practicing allergists in the United States agrees that the removal of all CFCs is important for our environment, but some of the important medications that we use daily to help control and improve the quality of life of our patients with asthma could be jeopardized by this rule. Some of the medications on the list scheduled for removal are unique and at present, there is no substitute in an HFA device for patients depending on these medications on a daily basis. This is different from the rulings on inhaled corticosteroids and albuterol. When three agents in HFA formulation were approved for use, then the CFC versions were to be removed from the marketplace. One example on the list of a unique agent is cromolyn sodium. This agent is the only non-steroid inhaler for control of asthma in the US. Many of our patients prefer a non-steroid alternative for asthma control. It also is extremely effective for patients not able to tolerate albuterol in the prevention of exercise-induced bronchospasm. It also shows response in the prevention of asthma triggered by animals. Many of our patients would be impacted with poorer control of their asthma with removal of this medication prior to the development of an HFA formulation.

Pirbuterol, a short-acting beta agonist, is unique due to its device. It is the only rescue medication for asthma in a breath actuated device available in the US. Some of our patients are not able to use a regular metered-dose inhaler as they can't coordinate actuating and breathing. This device allows them to receive optimal dosage of their rescue medication without worrying about using the device correctly. In a life-threatening asthma attack, this could make a great difference.

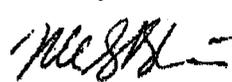
We, the American College of Allergy, Asthma, and Immunology believe that each asthma medication on the list for removal should be evaluated separately by the FDA. As mentioned above, some of these medications are unique and removal from the market will put a hardship on our patients. These agents should be continued to be produced and available by a prescription until their HFA formulations are developed and approved for use by the FDA.

Sincerely,



Daniel Ein, MD
President

Sincerely,



Michael S. Blaiss, MD
Chairman
Asthma & Respiratory Diseases Committee

2006N-0454

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