

# Congress of the United States

Washington, DC 20515

May 21, 2012

The Honorable Margaret A. Hamburg, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Hamburg:

As members of the bi-partisan Congressional Asthma and Allergy Caucus, we strongly urge you to allow the release of more than one million remaining units of Primatene® Mist, currently stored in a California warehouse, so that they can be made available to the millions of Americans suffering the disabling effects of asthma. Further, we are encouraged by your willingness to work with the Primatene® Mist manufacturer to develop an alternative (non-CFC) over-the-counter emergency inhaler.

As you know, Primatene® Mist, the only low cost over-the-counter emergency inhaler, is no longer available to the American people.

It appears as if the government's underlying decision to remove Primatene® Mist from the market was motivated by the EPA's concerns for the purported environmental impact of the CFCs in the inhalers to comply with the Montreal Protocol. The removal does not appear to be for a health or safety concern with Primatene® Mist. We are deeply concerned about the potentially serious plight of asthmatics who find themselves without an affordable, easily accessible, over-the-counter emergency inhaler, Primatene® Mist. For more than 50 years, Primatene® Mist was available in drugstores throughout America. Now, with the withdrawal of Primatene® Mist from the market, an asthmatic must first see a doctor, obtain a prescription, and purchase Albuterol. The cost of Albuterol is two to three times greater than that of Primatene® Mist.

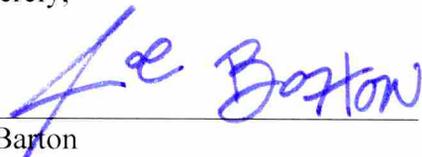
During an asthma attack, patients are desperately struggling to breathe. They cannot walk into a physician's office, obtain a prescription, and fill a prescription at a cost of \$50.00 to \$65.00. Primatene® Mist is a readily available emergency inhaler that costs \$20.00. While we appreciate that drug companies have programs to assist indigent patients with the high cost of prescription drugs, such programs are not a substitute for having a lower cost over-the-counter product in the marketplace. It is not just the cost of the prescription that our constituents face, but also the expense and inconvenience of having to take time off from work, travel to the doctor's office, and obtain a prescription. Even after the prescription is obtained, many Americans cannot afford to pay the higher cost of the prescription medication.

The environmental concern cited by the government is mitigated by the fact that the CFC used in the production of Primatene® Mist was an “essential use” permissible under the Montreal Protocol. The amount of CFC that would be expended with the use of the last million units of Primatene® Mist has already been calculated and designated as “essential use.” It does not matter when the release of CFC occurs. The environmental goal of not using CFC’s in the product of Primatene® Mist was achieved in August of 2011 when the manufacturer shut down its production facility.

Also, there still remain two Albuterol inhalers that utilize CFCs on the market.

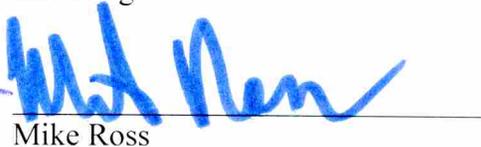
As co-chairs of the bi-partisan Congressional Asthma and Allergy Caucus, we urge you to allow the continuation of the sale of Primatene® Mist until all retail supplies are exhausted, and we urge the FDA to expeditiously approve a CFC free over-the-counter inhaler for asthmatics.

Sincerely,

  
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Joe Barton

  
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Eliot Engel

  
\_\_\_\_\_  
Michael Burgess

  
\_\_\_\_\_  
Mike Ross

Cc: Hon. Kathleen Sibelius, HHS  
Hon. Lisa Jackson, EPA Administrator  
Hon. Cynthia Giles