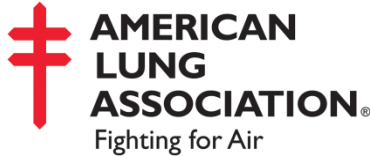




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Asthma and Allergy  
Foundation of America



November 23, 2011

The Honorable Lisa P. Jackson  
Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Dear Administrator Jackson:

On behalf of the undersigned medical and public health organizations, we strongly urge you to move forward with the December 31, 2011, phase-out of CFC-propelled over-the-counter epinephrine (Primatene Mist CFC) from the U.S. market. We strongly believe that a firm transition date is in the best interest of patients with asthma.

As you know, in response to concerns about the growth of the hole in the ozone layer and its potential global health and environmental effects, the Montreal Protocol treaty was signed by the United States in 1987 and later ratified by the U.S. Senate. The Montreal Protocol created a process to remove non-essential ozone depleting chemicals from the market place. Chlorofluorocarbons (CFCs) were one of the many ozone depleting substances covered by the treaty.

As you also know, prior to the Montreal Protocol, CFCs were commonly used as a propellant in household and medical aerosol products. One of the more challenging technical aspects of the transition was developing CFC alternatives for aerosolized respiratory medicines to treat asthma and other lung diseases. Due in large part to industry innovation, the United States has successfully managed the transition from CFC to CFC-free products for drugs used to treat asthma and other respiratory conditions.

We are aware Members of Congress have requested that EPA allow the existing stock of Primatene Mist CFC be sold after the December 31, 2011 deadline and until the stock is depleted. We urge you to reject this request for the following reasons.

### Epinephrine is suboptimal care for the treatment of asthma.

Asthma is a common and potentially serious health condition that impacts millions of Americans. Fortunately there are effective medications that can be used to manage patients with asthma. Several expert panels have produced recommendations on the treatment of patients with asthma. None of the expert guidelines recommend the use of over-the-counter medications--like Primatene Mist--to treat asthma. The National Asthma Education and Prevention Program (NAEPP), an expert panel convened by the National Institutes of Health, has issued treatment guidelines for management of asthma. NAEPP recommends against the use of epinephrine for treating asthma exacerbations stating:

“Drugs of choice for acute bronchospasm. Inhaled route has faster onset, fewer adverse effects, and is more effective than systemic routes. The less beta2-selective agents (isoproterenol, metaproterenol, isoetharine, and **epinephrine**) are not recommended due to their potential for excessive cardiac stimulation, especially in high doses. (*emphasis added*)(1)

We strongly encourage any patient who uses over the counter medications--like Primatene Mist CFC--to treat his/her asthma to seek a healthcare provider who can help the patient develop an asthma management plan and recommend more effective and safer medications to manage the asthma.

### A Firm Transition Date will Help Ensure an Orderly Transition

We note that delay letter requests Primatene Mist CFC be permitted to be sold after the December 31, 2011 deadline, until the product stockpile is deleted. Such an imprecise transition deadline will create confusion for patients and undermine efforts for an orderly and effective transition. It will invariably lead to significant variation in product availability. More importantly, a rolling enforcement deadline will prevent pharmacists and other health professionals from being able to deliver a nationally coordinated, timely message to Primatene Mist CFC users on their treatment options.

### Consistent Transition Process

This is not the first time industry has petitioned the EPA to be granted an enforcement extension beyond the established deadline. Manufacturers of CFC- containing medical products sought similar exemptions earlier in the transition process. The EPA rejected those earlier petitions. We also note that Armstrong Pharmaceuticals sought and received a one-year extension of the transition date. We believe Armstrong has had sufficient time to prepare for a final transition date of December 31, 2011. FDA determined in 2008 that epinephrine should be phased out. We have been working for more than three years for this orderly transition.

### The Ozone Layer

Lastly, we note the hole in the ozone layer still exists. Thankfully, scientists project that due to continuing reductions of on ozone-depleting substances; the hole in the ozone layer is stabilizing and is expected to recover in the coming decades. The success of the Montreal Protocol should be celebrated and give the EPA firm resolve to move

forward the established, orderly transition schedule for continued emissions reductions in ozone depleting substances.

We hope you will keep our thoughts in mind as you evaluate any request to delay the phase-out deadline.

Sincerely,

American Thoracic Society  
American Lung Association  
American Association of Respiratory Care  
Asthma and Allergy Foundation of America  
American Association of Cardiovascular and Pulmonary Rehabilitation  
National Home Oxygen Patients Association  
COPD Foundation

1) National Asthma Education Prevention Program– Expert Report 2 (1997) p. 64 figure 3-2.