



International Pharmaceutical Aerosol Consortium

THE NEED TO TRANSITION CFC-BASED EPINEPHRINE MDIS

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Recent legislative proposals seek to delay or suspend the transition of chlorofluorocarbon (CFC)-based epinephrine metered-dose inhalers (MDIs) (brand name *Primatene Mist*). ***IPAC strongly opposes these proposals as (i) contrary to the United States' important and longstanding international commitments to protect the stratospheric ozone layer, and (ii) unnecessary to protect the health of asthma patients. In this regard, we wish to share the following perspectives on this important issue.***

- ▶ The phase-out of *Primatene Mist* and other ozone-depleting MDIs was initiated more than two decades ago in response to the mandates of the Montreal Protocol. The “essential use” process established under the Montreal Protocol has provided the MDI industry ample time to reformulate and seek approvals of CFC-free alternatives. After long ago “seeing the writing on the wall”, MDI manufacturers worked diligently to research and develop CFC-free products. Most companies (including all IPAC members) have invested hundreds of millions of dollars to accomplish this important objective.
- ▶ The December 31, 2011, phase-out date for CFC-based *Primatene Mist* was established by FDA in 2008 (under the prior administration), and was based upon an extensive administrative record that included input from key experts, including patient and physician stakeholders. This deadline has provided three full years to transition patients to one of the several CFC-free alternatives available.
- ▶ Available patient assistance programs (and product samples) will help many users of *Primatene Mist* successfully transition to safe and effective CFC-free alternatives.
- ▶ Even if Congress were to ignore FDA's findings by overriding the ban on *Primatene Mist*, it would only briefly forestall the inevitable. Due to a global ban on CFC production, safe and adequate supplies of pharmaceutical-grade CFCs do not exist for the continued manufacture of *Primatene Mist*. It is therefore important for users to transition now.
- ▶ **IPAC respectfully urges the Congress to ensure that the phase-out of CFC-based epinephrine MDIs proceeds as planned so that patients and consumers are not subjected to unnecessary risks or uncertainty.**

The International Pharmaceutical Aerosol Consortium (IPAC) is a group of pharmaceutical companies that manufacture metered dose inhalers (MDIs) and other products to treat respiratory illnesses, such as asthma and chronic obstructive pulmonary disease (COPD). ***IPAC's members are: AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, GlaxoSmithKline, Sunovion and Teva.*** In response to the important environmental objectives of the Montreal Protocol on Substances that Deplete the Ozone Layer, IPAC actively promoted a smooth and safe transition to chlorofluorocarbon (CFC)-free alternatives, that balances patient health and environmental concerns.