

Docket # 97N-0023



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Vice President

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Jm  
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May 28, 2002

National Headquarters:  
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L. Kirkwood  
Executive Officer

John D. Graham, Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
Executive Office Building  
17<sup>th</sup> Street and Pennsylvania Ave, N.W.  
Washington, D.C. 20503

Re: Use of Ozone Depleting Substances: Essential  
Use Determinations; RIN 0910-AA99

Dear Mr. Graham:

The American Lung Association, convener for the Stakeholders Group on MDIs (representing patient and health care provider organizations concerned with respiratory disease) understands that an FDA Final Rule on the transition out of chlorofluorocarbon (CFC) -based metered dose inhalers (MDIs) is now under review at the Office of Information and Regulatory Affairs. We encourage publication of the Final Rule as soon as possible, specifically in advance of the next meeting of the Open-Ended Working Group to the Parties to the Montreal Protocol, which takes place in July. We also urge you to make the effective date for the rule December 31, 2002.

The Proposed Rule suggested an effective date one year after publication of the Final Rule. However, the Rule has now been pending for over two and a half years. To allow the transition to proceed and to demonstrate good faith to the Parties to the Montreal Protocol, we urge that you to consider altering this timeframe to make the procedural elements of the Final Rule (i.e., all but the essential use listings in paragraph (e) of the Rule) effective on December 31, 2002.

When You Can't  
Breathe, Nothing  
Matters®

Nearly 100 years, the American Lung Association, Association affiliates throughout the United States and the American Thoracic Society have worked together in the fight against lung disease.

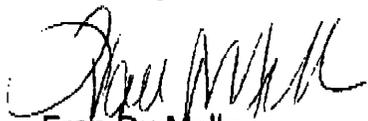
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The absence of a final U.S. Transition Policy continues to undermine educational initiatives for patients and health care providers about the transition to CFC-free MDIs. Without a national transition policy in place, uncertainty and possible patient and health care provider confusion will persist. A systematic, cooperative effort on the part of the health care providers, patients and their respective organizations, pharmaceutical companies and the government is needed. This, in turn, requires that a regulatory-driven transition policy be in place in the U.S. as soon as possible.

Thank you for your consideration of this request.

Sincerely,



Fran Du Melle  
Executive Vice President, Mission

Cc: Claude A. Allen  
Deputy Secretary  
Department of Health and Human Services

Lester M. Crawford, Jr., D.V.M., Ph.D.  
Deputy Commissioner  
Food and Drug Administration

Jeffrey R. Holmstead  
Assistant Administrator for Air and Radiation  
Environmental Protection Agency