



August 16, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Docket No. 2003P-0029
Use of Ozone-Depleting Substances; Removal of
Essential-Use Designations**

Dear Sir/Madam:

On behalf of the US STAKEHOLDERS GROUP ON MDI TRANSITION, I am pleased to submit the attached Comments to the above-referenced rulemaking proposing removal of the essential-use designation for albuterol metered-dose inhalers.

The US STAKEHOLDERS GROUP ON MDI TRANSITION is a consortium of nine leading patient and medical professional associations, representing more than 25 million Americans who suffer from asthma, chronic obstructive pulmonary disease (COPD), and other respiratory diseases. Since 1996, we have sought to ensure a transition to CFC-free MDIs that properly balances the threat to public health posed by stratospheric ozone depletion with the needs of patients who rely on inhaled therapies.

Now that the question of whether or not CFC-containing MDIs should be removed from the market has been resolved, setting a precise effective date for removal of CFC albuterol is less an environmental or health matter as it is an administrative one, albeit with significant political and economic implications. Foremost, FDA must judge how long CFCs will be reliably manufactured and available. If doubt remains as to whether new CFCs can be obtained after December 31, 2005, FDA must determine how the continued use of CFCs in albuterol will affect all remaining CFC-containing MDI products. Next, FDA must establish a timeline for manufacturing capacity of HFA albuterol MDIs, and determine what period of time is needed to develop and deploy an adequate program to educate patients, physicians and other healthcare providers about transition.

Regarding the inevitable cost implications of transition, we call for FDA to ameliorate negative impacts, specifically at the patient level, by insisting on adequate patient education and assistance programs, including appropriate innovative measures that reflect the importance of the albuterol moiety.

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We look forward to providing our collective expertise to FDA as it continues its careful consideration of this matter.

Sincerely,



Fran Du Melle
Convener, US STAKEHOLDERS GROUP ON MDI TRANSITION

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ON BEHALF OF THE MEMBER ORGANIZATIONS

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American Academy of Allergy, Asthma and Immunology (AAAAI)
American Academy of Pediatrics (AAP)
American Association for Respiratory Care (AARC)
American College of Allergy, Asthma and Immunology (ACAAI)
American College of Chest Physicians (ACCP)
American Lung Association (ALA)
American Thoracic Society (ATS)
Asthma and Allergy Foundation of America (AAFA)