Allergy & Asthma Network
Mothers of Asthmatics

October 28, 2003

Dockets Management Branch
U.S. Food and Drug Administration
Department of Health and Human Services
HFA-305
5600 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 03P-0029
Citizen Petition Submitted by US Stakeholders Group on MDI Transition Requesting that the FDA Initiate a Rulemaking to Remove Albuterol CFC MDIs from the List of Essential Uses of Ozone Depleting Substances

Dear Commissioner McClellan:

As you know, the Montreal Protocol on Substances that Deplete the Ozone Layer requires the phase-out of all ozone depleting substances, including chlorofluorocarbons (CFCs). CFC-containing albuterol metered-dose inhalers (MDIs) were exempted from the Montreal Protocol's phase-out schedule as an "essential use" of CFCs so long as no "technically and economically feasible alternatives" were available from the "standpoint of environment and health". The US Clean Air Act, which implements US obligations under the Montreal Protocol, requires that CFC MDIs remain essential only so long as no safe and effective alternatives are available. Two CFC-free albuterol MDIs are now available to patients with asthma and COPD. These MDIs have been determined by FDA to be both safe and effective. Other key criteria established by FDA for the phase-out of CFC albuterol MDIs have also been met. On behalf of the Allergy & Asthma Network/Mothers of Asthmatics I strongly urge FDA to publish a proposed rule to remove CFC albuterol MDIs from its list of essential uses.

I remain particularly concerned that an uncertain future supply of pharmaceutical grade CFCs as well as the necessary component parts for CFC-containing MDIs could threaten the smooth transition for patients from CFC-containing MDIs to CFC-free medicines. Our organization, which represents millions of asthma patients and their families, joined other prominent professional and patient organizations to submit a Citizen Petition to you earlier this year. That petition states that there is considerable uncertainty as to how many CFC producers will continue to supply pharmaceutical-grade CFCs. We know there remains only one supplier of pharmaceutical grade CFC11 and CFC12. That supplier, in the Netherlands, is scheduled to shut down operations by order of the government by 2005 or earlier. In addition, supplies of other

CFC MDI components such as valves and canisters are becoming increasingly uncertain.

Pursuant to the Montreal Protocol, several pharmaceutical manufacturers invested considerable time and significant resources to develop CFC-free medicines for asthma and COPD patients. Manufacturers of MDI component parts for CFC-free MDIs have also invested extensively in the development and manufacture of new technologies. I believe that these companies should be recognized and rewarded for investing in new medicines and technologies at the request of the US government rather than penalized by failure of the FDA to propose a rule to remove CFC albuterol MDIs from the FDA list of essential uses.

I therefore urge FDA to act as requested by the Citizen Petition submitted by the US Stakeholders on MDIs and remove CFC-containing albuterol MDIs from its list of essential uses. In addition, FDA should offer strong support of the European Community's draft decision that was tabled during the July 2003 meeting of the Montreal Protocol Parties. This decision establishes firm deadlines for the essential use process for MDIs. Such action by the FDA will lead to a smooth and orderly transition to CFC-free alternative MDIs and is in the best interest of patients with asthma and COPD who rely on these medicines.

Sincerely,

Ellen Lathem
Chief Operating Officer

Cc: Senator John Warner
Senator George Allen
Senator Mike DeWine
Senator Edward Kennedy
Representative Tom Davis
Representative Patrick J. Kennedy
Representative Cliff Stearns