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September 3, 2003

By Hand
Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane Room 1061
Rockville, Maryland 20852

RE: SUPPLEMENTAL SUBMISSION RE: CITIZEN PETITION SUBMITTED BY THE US STAKEHOLDERS GROUP ON MDI TRANSITION (FDA DOCKET NO. 03P-0029)

Dear Sir or Madam:

The International Pharmaceutical Aerosol Consortium (IPAC)[1] writes to supplement its initial comments, filed March 7, 2003 pursuant to 21 CFR § 10.30(d), in response to the Citizen Petition submitted by the US Stakeholders Group on MDI Transition (the "Stakeholders' Petition"). The Stakeholders' Petition requests the Commissioner of Food and Drugs to initiate notice and comment rulemaking to remove albuterol MDIs from the list of essential uses of ozone-depleting substances ("ODS") set forth in 21 CFR § 2.125(e)(2). On July 28, the FDA provided an interim response to the Stakeholders' Petition stating that the Agency has not yet been able to reach a final decision on the petition "because it raises significant and complex issues requiring extensive review and analysis by Agency officials." The interim response did not detail the issues to be addressed, nor did it provide any guidance regarding the anticipated

[1] IPAC is an association of leading manufacturers of metered-dose inhalers (MDIs) used for the treatment of asthma, chronic obstructive pulmonary disease (COPD), and other respiratory illnesses. IPAC was created in response to the mandates of the Montreal Protocol. Since its inception, IPAC's core objective has been to promote a smooth and efficient CFC MDI transition that balances public health and environmental protection.

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process and timing for FDA's consideration of the important issues raised in the Stakeholders' Petition. Therefore, IPAC would like to take this opportunity to emphasize the crucial need for prompt action on the Stakeholders' Petition, and to strongly urge the FDA to initiate the rulemaking process on albuterol CFC MDIs.

As noted in its initial submission, IPAC supports the process established by the Final Rule for evaluating the essentiality of CFC MDIs and believes that this process was carefully designed to ensure that patients will be adequately protected throughout the transition. Further, IPAC agrees with the Stakeholders that the phase-out of albuterol CFC MDIs would advance the international goal of protecting the earth's ozone layer while ensuring patient care.

Indeed, the international community is now considering measures to ensure an effective and timely closure to the CFC MDI transition in the developed world. During the July 2003 meeting of the Montreal Protocol Parties, a decision was tabled that would establish firm deadlines for the essential use process for MDI products. Under the decision, after 2005 no essential use CFC volumes would be authorized by the international body for CFC MDI products where the only active ingredient was albuterol. In addition, the decision proposes to cease authorization after 2007 of essential use CFC volumes for all MDIs intended for sale or distribution in developed countries. The proposed deadlines take into account the worldwide availability of CFC-free products and, importantly, are subject to a narrow exception that would ensure patient safety. *To meet the first deadline, the FDA must proceed now with its rulemaking on albuterol non-essentiality.* IPAC fully supports adoption this year of the draft decision and believes that concrete measures should be undertaken now to plan for, and accomplish, an end to the CFC MDI transition.

IPAC appreciates that the Stakeholders' Petition raises important, complex patient health issues and presents some challenges from a health economic perspective. However, IPAC firmly believes that initiating now the rulemaking as the Stakeholders propose and thereby promoting a transparent, thorough consideration of these issues will benefit all interested stakeholders, as well as the environment. IPAC remains committed to the CFC MDI transition in the United States and would be pleased to serve as a resource of relevant information and analyses during this process. We look forward to working with FDA on these critical issues.

Sincerely,

Joseph Ferrara
IPAC Chair

cc: Dr. Robert Meyer, FDA
Dr. Eugene Sullivan, FDA
Ms. Drusilla Hufford, EPA
Mr. Jeffry Burnam, US Dept. of State