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INTERNATIONAL PHARMACEUTICAL AEROSOL CONSORTIUM

1301 K Street NW • Suite 900 • East Tower • Washington DC • 20005-3317
Telephone +1 202 230 5189 • Telefax +1 202 230 5300
Internet: http://www.ipacmdi.com

March 7, 2003

By Hand

Dr. Robert Meyer, Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research
Food and Drug Administration
Division of Pulmonary Drug Products
5600 Fishers Lane (HFD-570), Room 10B45
Rockville, Maryland 20857

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

Dear Dr. Meyer:

The International Pharmaceutical Aerosol Consortium (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. To that end, IPAC has been engaged on issues related to the CFC MDI transition in the United States and other countries for more than a decade.

These comments are submitted, 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, based on FDA's Final Rule

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of July 24, 2002 (67 FED. REG. 48370), to remove albuterol MDIs from the list of essential uses of ozone-depleting substances ("ODS") set forth in 21 CFR § 2.125(e)(2). IPAC supports the process set forth in 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.

IPAC therefore welcomes the submission of a Petition by major patient and physician stakeholders. The Stakeholders have a strong interest in promoting a smooth transition that protects patient health, and IPAC commends their dedicated efforts to educate the public on the MDI transition over the past several years. 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.

The Stakeholders' Petition requests that FDA evaluate the essentiality of albuterol CFC MDIs based on the criteria set forth in 21 CFR § 2.125(g). While IPAC cannot comment on whether each of the criteria articulated in this section have been met, it believes that the best way for FDA to make that assessment is to issue a proposed rule and thereby open up the process for public comment. IPAC therefore agrees that it is appropriate for FDA to issue a proposed rule as requested by the Stakeholders within the timeframe proposed. This is particularly true since two CFC-free albuterol products have been available on the market in the United States for at least a year.

Given the wide availability of CFC-free albuterol products in most developed countries, IPAC has proposed at the international level that the Montreal Protocol not authorize CFCs for albuterol MDIs after 31 December 2005 in the developed world. To meet this deadline, the FDA must proceed with its rulemaking on albuterol non-essentiality as the Stakeholders propose. It is important to note that other developed countries (*e.g.*, Australia, Canada, Japan, and eleven EU Member States) have already determined the use of CFCs in albuterol MDIs to be non-essential. Albuterol MDIs represent the largest use of CFCs for MDIs in the US and, therefore, determining albuterol to be non-essential would result in a significant reduction in US demand for CFCs and would reinforce US leadership in the Montreal Protocol.

Finally, prompt action by FDA to initiate this process would send an important signal to MDI companies that FDA is serious about transitioning the US market, thus reinforcing companies' incentive to sustain their commitment to the reformulation effort.

IPAC appreciates the opportunity to submit these comments and looks forward to continuing to actively engage in the transition process.

Sincerely,

Joseph Ferrara
IPAC Chair

cc: Dr. Eugene Sullivan, FDA
Ms. Drusilla Hufford, EPA
Dockets Management Branch (Docket No. 03P-0029)