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April 01, 2004

1300 '04 APR -8 09:38

Dr. Lester Crawford, Acting Commissioner
U.S. Food and Drug Administration
1471 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

**RE: Docket No. 03P-0029
Citizen Petition on Removal of Essential Use Designation for
Albuterol MDIs**

Dear Dr. Crawford:

According to a timeline published in the Federal Register on December 22, 2003, the U.S. Food and Drug Administration was to issue by March 2004 a proposed rule for considering removal of the essential use designation for metered-dose inhalers ("MDIs") containing the active moiety albuterol. The US STAKEHOLDERS GROUP ON MDI TRANSITION, a coalition of organizations representing patients, physicians and other healthcare professionals specializing in respiratory care, **respectfully request FDA promptly issue a notice of proposed rulemaking.**

STAKEHOLDER interest in prompt rulemaking is not merely procedural. Patient health is at risk due to uncertainties about long-term, reliable supply of pharmaceutical-grade CFCs and MDI components. We assumed that FDA shared our concern in this regard because its published timetable is set to complete rulemaking sufficiently in advance of December 31, 2005 when Honeywell will close the last remaining CFC manufacturing plant in Weert, The Netherlands. But ensuring that patients are in fact protected requires the Agency to meet its own schedule for issuing proposed and final rules.

As FDA has tentatively concluded already, the criteria for removing the essential use designation for albuterol have been met. Given the uncertainty of supply after 2005, and the lead time required by manufacturers to produce sufficient HFA product, it is critical that FDA immediately commence rulemaking.

We look forward to working with the Agency to finalize a 2005 effective date for eliminating CFC albuterol MDIs.

Sincerely,

Fran Du Melle
Senior Vice President
Convener, US STAKEHOLDERS GROUP ON MDI TRANSITION

03P-0029

C7

cc: Mr. Tommy G. Thompson
Mr. Claude Allen
Mr. Richard H. Carmona
Mr. Peter Pitts
Mr. William Steiger
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