J. Stanley Hull
Senior Vice President
US Pharmaceuticals – RTP

GlaxoSmithKline

GlaxoSmithKline
Five Moore Drive
PO Box 13398
Research Triangle Park
North Carolina 27709-3398

Tel. 919 483 7427
Fax. 919 315 3183
Stan.Hull@gsk.com
www.gsk.com

November 10, 2003

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

Re: Docket No. 03P-0029
Citizen Petition: Requesting FDA to Initiate Rulemaking on CFC Albuterol MDIs

Dear Sir or Madam:

GlaxoSmithKline (GSK) hereby submits additional supplementary information to our comments on the Citizen Petition submitted by the US Stakeholders Group on MDI Transition.[1] The purpose of this second supplemental submission is to inform FDA that, effective November 5, 2003, GSK has frozen the wholesale acquisition cost[2] for GSK's CFC-free albuterol metered-dose inhaler (MDI), Ventolin HFA. GSK will maintain this freeze at least through December 31, 2007.

- GSK's decision to freeze the wholesale acquisition cost for its CFC-free albuterol MDIs is one of several voluntary measures that the company has taken to facilitate patient access to necessary medications and assist the U.S. Government in meeting its commitment to phase out ozone-depleting substances. GSK also continues to participate in the Orange Card, Together Rx Card, Bridges to Access™, and Promise programs – discussed in detail in GSK's prior submissions – to assist low-income patients in obtaining needed medications. In addition, at the time of transition to CFC-free albuterol MDIs, GSK will make two million complimentary full-size samples of Ventolin HFA available to physicians, who may choose to reserve these inhalers for their lower-income patients.

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1 GlaxoSmithKline Comments on the January 29, 2003 Citizen Petition submitted by the US Stakeholders Group on MDI Transition, July 2, 2003, Docket 2003P-0029-C3.

2 "Wholesale acquisition cost" is the listed price to wholesalers and warehousing chains, not including prompt pay discounts, stocking or distribution allowances, or other discounts, rebates, or chargebacks. List prices may not represent prices charged to other customers.

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GSK hopes that this supplemental information will assist FDA in its decision-making process.

Sincerely,

Stan Hull

Stan Hull
Senior Vice President
U.S. Pharmaceuticals

cc: Mark B. McClellan
Commissioner, Food and Drug Administration

Jeffrey R. Holmstead, Assistant Administrator for Air and Radiation
Environmental Protection Agency

John F. Turner, Assistant Secretary for Oceans and
International Environmental and Scientific Affairs
Department of State

James L. Connaughton, Chairman
Council on Environmental Quality

John D. Graham, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget