

J. Stanley Hull
Senior Vice President
US Pharmaceuticals - RTP

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May 3, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
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Re: Docket No. 03P-0029
Citizen Petition: Requesting FDA to Initiate Rulemaking
on CFC Albuterol MDIs

Dear Sir or Madam:

The purpose of this letter is to clarify the information submitted by GlaxoSmithKline (GSK) in its November 10, 2003 letter to this docket. In that letter, GSK stated that: "... 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." We want to clarify that GSK will provide two million free samples of Ventolin HFA each year, beginning on or before the effective date for CFC albuterol non-essentiality.

This decision to provide two million free samples annually, along with our decision to freeze the wholesale acquisition cost for HFA Ventolin (also detailed in our November 10, 2003 submission to the docket), and our assistance to lower income patients through numerous patient access programs (described in our July 2, 2003 and August 5, 2003 submissions to the FDA docket) underscore GSK's commitment to ensure that patients will have access to the treatments they need when CFC albuterol MDIs are phased out.

We hope that this clarification helps FDA in its consideration of the essential use status of CFC albuterol MDIs.

Sincerely,

A handwritten signature in black ink that reads "Stan Hull" with a small flourish at the end.

Stan Hull
Senior Vice President
U.S. Pharmaceuticals

03P-0029

SUP 7

cc: Lester M. Crawford
Acting 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