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Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
HFA-305  
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Rockville, MD 20852

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**Re: NAS 0; Not Product Specific**

**General Correspondence: Docket No. 03P-0029**

**Citizen Petition: Requesting FDA to Initiate Rulemaking to Remove CFC Albuterol MDIs from FDA's List of Essential Uses of Ozone-Depleting Substances**

Dear Sir or Madam:

GlaxoSmithKline (GSK) hereby submits the following supplement to our comments on the January 29, 2003 Citizen Petition submitted by the US Stakeholders Group on MDI Transition.<sup>1</sup> The purpose of this supplemental submission is to expand our discussion of "Bridges to Access"<sup>2</sup>, GSK's patient assistance program.

The overall goal of Bridges to Access is to ensure that no low-income patient will be denied access to GSK products simply because he or she cannot afford to pay. Eligibility requirements for Bridges to Access are specifically designed to help people who are not eligible for prescription drug benefits through any private or public insurer/payer program. To qualify, the patient must be a resident of the United States, live in either a single person household with an income of not more than \$25,000 or a multi-person household with total incomes not more than 250 percent of the federal poverty level, and not eligible for other prescription drug benefits.<sup>3</sup>

Bridges to Access works by using "advocates" to enroll patients and assist in shepherding them through the program. An advocate is typically a physician, nurse,

<sup>1</sup> 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 ("GSK Comments").

<sup>2</sup> See GSK Comments at section 3.7.2.1.1.4, p. 15.

<sup>3</sup> In Alaska and Hawaii, 250% of the federal poverty level is applied to all patients.

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or social worker, but may be any healthcare worker involved in the patient's care. Because the advocate is familiar with the patient, he or she is aptly suited for meeting their specific needs by expediting documentation through the appropriate channels and insuring that the patient receives his or her medication that same day. There is no charge to the patient or the advocate for this service aside from a five-dollar co-pay per prescribed drug per fill at the retail pharmacy.

Many patients are able to obtain more comprehensive prescription and medical coverage as a result of Bridges to Access. Because the program includes reimbursement support services designed to make patients aware of other prescription drug benefits, advocates can often help patients in gaining assistance from Medicare, Medicaid, Children's Health Insurance Programs, State Elderly Drug Assistance Programs, and other assistance programs. Patients who qualify for aid under these prescription drug plans will continue to receive interim assistance through Bridges to Access while their enrollment application is being processed.

Bridges to Access is a vital component of GSK's longstanding commitment to ensuring low-income patients' access to medicine. In 2002 GlaxoSmithKline provided over \$168 million worth of medicines to 407,000 patients. This program, along with the other assistance programs discussed in our initial comments, will substantially reduce the possibility that particularly vulnerable patient populations will be denied access to needed treatment as a result of FDA action to remove albuterol from its essential use list.

We hope that this supplemental information will be of use to FDA in its decision-making process.

Please do not hesitate to call me at (919) 483-4461 if you require any further information.

Sincerely,



Andrew Gustafson, Ph.D.  
Vice President  
Regulatory Affairs

cc: John K. Jenkins, Director  
Office of New Drugs, Food and Drug Administration

Robert J. Meyer, Director  
Office of Drug Evaluation II, Food and Drug Administration

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