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September 8, 2003

Dockets Management Branch
U.S. 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 Submitted by U.S. Stakeholders Group on MDI Transition
Requesting that the FDA Initiate a Rulemaking to Remove Albuterol CFC MDIs from
the List of Essential Uses of Ozone Depleting Substances – Economic Analysis of
Impact on Patients and Payers

Dear Sir or Madam:

On January 29, 2003, the U.S. Stakeholders Group on MDI Transition filed a *Citizen Petition* requesting that the FDA issue a proposed rule to remove albuterol chlorofluorocarbon (“CFC”) metered-dose inhalers (“MDIs”) from the FDA’s list of essential uses of ozone depleting substances. As part of the FDA’s analysis prior to removing an essential use, the FDA is considering the impact of costs on patients’ access to treatment.

In that regard, we submit the enclosed analysis entitled “The Impact on Patients and Payers of Designating Albuterol a Non-Essential Use of an Ozone Depleting Substance.” We prepared this report to assist the FDA in determining whether albuterol CFC MDIs should be removed from the FDA’s list of essential uses of ozone depleting substances.

National Economic Research Associates, Inc. (“NERA”), an international firm of economists, was retained by GlaxoSmithKline to analyze the economic issues raised by the FDA in connection with designating albuterol non-essential. Our research represents our independent views on the current and projected market environments for selling albuterol. NERA specializes in applying microeconomics to complex business and legal matters. For over 40 years, NERA economists have contributed to understanding the economic issues in business, legal, regulatory, and public policy forums.

2003P-0029

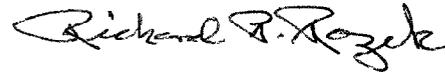
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Please contact me if you have any comments or questions.

Sincerely,



RPR:pmb

Enclosure

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

Eugene J. Sullivan, Medical Officer
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Donald R. Arbuckle, Deputy Administrator
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Dr. Mark B. McClellan (c/o Mary-Lacey Reuther, Special Assistant to the
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Food and Drug Administration

Dr. Stuart Nightingale, M.D., Chief Medical Officer
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