STATE OF NEW YORK
DEPARTMENT OF HEALTH
Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

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Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

December 13, 2004

Dockets Management Branch
Docket Number 03P-0029
U.S. Food and Drug Administration
Room I-23
12420 Parklawn Drive
Rockville, MD 20857

Re: FDA Proposed Rule, Docket No. 2003P-0029
Food and Drug Administration (FDA)
Notice of Proposed Rulemaking (NPR) – *Federal Register* July 23, 2004

To Whom It May Concern:

On June 9, 2004, the FDA released a notice in the *Federal Register* seeking public comment on a proposal to withdraw "essential-use" status for chlorofluorocarbon ("CFC") containing albuterol metered dose inhalers ("MDIs"). This notice was issued because two alternative, non-CFC based, brand albuterol inhalers are now available: Proventil HFA and Ventolin HFA. If the essential-use designation is removed, albuterol inhalers containing ozone-depleting substances such as CFC cannot be marketed after an appropriate transition period.

For the past several years, virtually all albuterol inhalers have been dispensed generically in the New York State Medicaid program. Implementation of the proposal will eliminate all generic albuterol inhaler products from the market, leaving only brand name products as the alternative. There will be only two manufacturers of albuterol inhalers and there may not be sufficient production capacity to generate the quantities needed: 42 million inhalers in the U.S. annually, with well over one million in the New York State Medicaid program alone. Manufacturers making the HFA albuterol inhalers will not increase production levels until the proposal is finalized.

HFA products are more expensive ($44 per each of the new inhalers versus $19 for the currently available generic CFC inhalers) because there is no option to fill generically. A review of NYS Medicaid claims for the period August 2003 through July 2004 indicates there were 1,018,613 claims for albuterol inhalant products (including brand and generic, and CFC and HFA). Total cost to the New York State Medicaid program for these products was $22,093,768. If the same number of claims were

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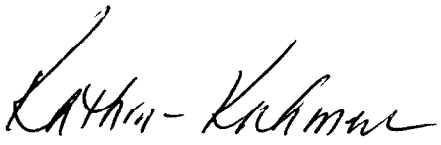
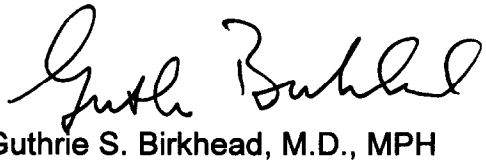
processed using only branded HFA products, the total cost would be $48,612,796, a 120% increase in cost to the New York State Medicaid program for albuterol inhalers.

Albuterol inhalers are an essential part of treatment for asthma and chronic obstructive pulmonary disease (COPD). Although the New York State Medicaid program is concerned about the significant increase in cost for the albuterol inhalers, we are especially concerned about the possibility of inadequate availability of this essential product to these very vulnerable populations. Until adequate quantities of non-CFC-based Albuterol inhalers are available for distribution in the United States, we ask that the FDA allow for additional time to make this a reality.

Sincerely,



Kathryn Kuhmerker
Deputy Commissioner
Office of Medicaid Management



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