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May 24, 2002

**VIA HAND DELIVERY**

Mr. Stuart Shapiro  
Policy Analyst  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
10235 New Executive Office Building  
725 17<sup>th</sup> Street, NW  
Washington, DC 20503

RE: FDA Final Rule on Ozone-Depleting Substances  
(OP 0910-AA99)

Dear Stuart:

Thank you for taking the time to talk with me earlier this week concerning FDA's final rule on use of ozone-depleting substances. As I mentioned, I was calling on behalf of GlaxoSmithKline (GSK), the world-leading developer and manufacturer of innovative medicines to treat respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD). Over the past decade, GSK has committed several millions of dollars – for research and development, clinical trials, re-engineering its production facilities, etc. – in order to convert its respiratory products into chlorofluorocarbon-free formulations, so as to enable the United States to meet its international obligations under the Montreal Protocol,

GSK very much supports the policy for making non-essentiality determinations proposed by FDA in its September 1, 1999 Notice of Proposed Rulemaking (NPR). We request that OMB expedite its review of this rule so that it can be issued as soon as possible. More than 30 months have passed since the NPR was issued, and the pharmaceutical industry, as well as physicians and patients, need the certainty that a final FDA policy will provide. Given that fewer than three dozen comments were received on the NPR, virtually none of which were adverse, issuing a final rule now should be non-controversial.

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Also, as I indicated in our telephone conversation, we have previously commented to FDA that the procedural elements of the rule be made effective upon publication. We understand that when the NPR was proposed back in 1999, and FDA thought that the final rule would *be* issued in a matter of months, it felt there was a need to defer entry into force of the final rule. But with the long passage of time since the NPR was published, there is no reason that the procedural elements of the rule – which govern future non-essentiality determinations – cannot now enter into force. Of course, as we stated in our previous submission to FDA, we recognize that there may be a need to defer for 3-4 months the effective date of the five non-essentiality determinations proposed in the NPR.

Finally, we ask that you consider the company's recommendation, made in its comments on the NPR, and echoed by other commenters, concerning the use of non-U.S. postmarketing use data. The NPR proposed that a minimum of one year of U.S. post-marketing use data be submitted, so that FDA could assess whether a CFC product is an acceptable replacement for CFC products. However, there is no medical or public health reason why postmarketing use data from virtually identical formulations used by patients in other countries should not count toward the one-year requirement.

Please give me a call if you need further clarification, or would like to discuss any of these points. We are grateful for your consideration on this important matter.

Sincerely,



James A. Losey