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Division of Dockets Management
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

August 18, 2004

Re: Docket No.2003P-0029 – Proposed Rule: Use of Ozone-Depleting
Substances; Removal of Essential-Use Designations

Dear Sir or Madam:

3M Company (3M) wishes to express to FDA and the public, its strong support of December 31, 2005 as an appropriate effective date for the elimination of the essential use designation for CFC albuterol MDI's. We are currently allocating the resources necessary to proceed with plans and activities to increase the supply and production capacity for Proventil HFA® (albuterol sulfate inhalation aerosol) metered-dose inhalers (MDI's) for the U.S. marketplace. These activities involve production upgrades at multiple manufacturing sites resulting in the capacity to produce up to 30 million Proventil HFA MDI's annually. 3M will have this production capacity in place by December 31, 2005. 3M is undertaking this supply and production capacity increase without waiting for further development in the above referenced rulemaking. Should the final rule indicate an effective date that is significantly beyond December 31, 2005, 3M may re-evaluate the timing for completing its production upgrades.

3M is committing to this production capacity because we understand that FDA's decision-making can be assisted by a firm commitment for production capacity from the manufacturers of HFA albuterol MDI's.

3M hopes this information will assist FDA in its decision-making on albuterol MDI essentiality. If you have any questions or need additional information, please do not hesitate to contact us.

Sincerely;

John Sampson
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C32