

# SCHERING CORPORATION

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

**RE: DOCKET NO.: 2003P-0029  
USE OF OZONE-DEPLETING SUBSTANCE; REMOVAL OF ESSENTIAL  
USE DESIGNATIONS**

Dear Sir or Madam,

Schering-Plough firmly supports the Montreal Protocol and the FDA's effort to coordinate removal of ozone-depleting substances (ODSs) in order to protect public health and the environment.

Schering previously submitted a document to the docket on August 13, 2004, asserting, among other key issues:

- our support for a December 2005 effective date for the final implementation of the rule to amend 21 CFR Part 2, Section 2.125, paragraph (e)(2)(i) to remove the essential-use designation for albuterol used in oral pressurized metered-dose inhalers,
- adequacy of supply of Proventil HFA™, and
- an outline of our Patient Access program that provides low-income, uninsured patients access to Proventil HFA .

Understanding the importance of the upcoming decision to finalize the albuterol CFC non-essential use date, we would like to take this opportunity to reinforce Schering's commitment to a successful transition from CFC to HFA albuterol products. We will be prepared to initiate the following programs in anticipation of an albuterol-CFC ban to help maintain patient access to non-ODS albuterol.

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1) MDI Production Capacity

As the U.S. leader in albuterol MDI production, and in support of our previous comments to the docket, Schering along with its manufacturing partner 3M, have invested in increased HFA manufacturing capacity to provide a 30 million HFA unit capacity by December 31, 2005.

2) Access

While Schering has previously provided information around its Patient Assistance Program, SP-Cares, we will implement an additional more focused initiative, designed to provide uninsured patients access to their rescue medications. Our plan centers on supporting the Federally Qualified Health Centers (FQHCs) who qualify for pharmaceutical discounts under the 340B Drug Pricing Program. Many of the FQHCs who qualify for these discounts are either unaware of them or have not taken advantage of them. Many of these clinics are located in areas with the greatest density of asthma prevalence and disadvantaged patients in the nation.

This program, called ASPIRE<sup>sm</sup>, is designed to provide a high level of focus on the most vulnerable asthma patients in the U.S. The ASPIRE<sup>sm</sup> program will be heavily supported by a public relations campaign designed to create awareness in the most disproportionately disadvantaged areas of the U.S.

- Schering will provide to accredited FQHCs (and other entities entitled to 340B pricing) Proventil HFA at a substantial discount, and we will agree to honor these prices through 2008.
- In addition, Schering will partner with a 501(c)3 organization, to target Community Health Centers across the country that serve the most needy. These centers are located across the country in urban and rural locations and include both large and small facilities.

Schering will donate Proventil HFA to these centers: 500,000 units of Proventil HFA to be available in the targeted centers 2 months pre-ban through six months post ban.. This donation represents approximately half of the 2004 demand from these types of clinics for our albuterol product.

In conjunction with our partner 501(c)3 organization, Schering will notify the centers of the availability of the free product, gather their requests for the product, and manage the shipment of the product to these individual facilities.

We believe this targeted distribution of Proventil HFA will put medication in the hands of those patients who need continued access to albuterol during the transition. We further believe that this will have a more significant impact than just providing untargeted samples and/or vouchers to physicians throughout the country with the assumption it will reach the hands of those who are most in need.

3) Proventil HFA Sampling Program

In addition to the 500,000 units that will be targeted for the ASPIRE<sup>sm</sup> program, Schering Plough is committing 500,000 professional samples to physician offices in the six months prior to the ban and 2 million units annually thereafter to be utilized in high areas of asthma prevalence across the U.S.

4) SP-Cares Patient Assistance Program

As we have previously stated, Schering also has the SP-Cares Patient Assistance Program that provides free product to low-income, uninsured patients. Schering is committed to ensuring that patients who need Proventil HFA have access and are adequately served. Reflecting this strong commitment to meeting patients' needs, Schering created the SP Cares Program in 1994 to provide primary care products, including Proventil HFA, free of charge for patients who qualify. Last year alone, Schering patient assistance programs provided products free of charge to more than 80,000 low income (those under 200% of the Federal Poverty Level) and uninsured patients. Further, we provided more Proventil brand of products to qualified individuals than any other Schering drug.

Access to the SP Cares program is broad and easy. Most people learn about the program through their doctors' office. SP Cares Patient Awareness and accessibility is a key objective of the communication program outlined below. Additionally, information about SP Cares is on the Schering-Plough corporate website, on PhRMA's website, and on the websites of numerous patient assistance clearinghouses.

5) Patient Awareness through Media and Patient Education

Schering-Plough is committed to helping maintain patient access to Proventil HFA after the albuterol-CFC ban. Reflecting this strong commitment to meeting patients' needs, SP will initiate an aggressive HFA awareness and access communication plan aimed specifically at patients in areas of high asthma prevalence utilizing English and Spanish materials to ensure that these patients are aware of and have access to the SP Cares program and the "ASPIRE" program. Utilizing education programs, public relations efforts stakeholder education, available in clinics, offices and pharmacies, Schering has committed to these key elements necessary for an orderly transition.

Through various partnerships with organizations such as the Asthma and Allergy Foundation of America (AAFA), and media initiatives targeted at minority and inner city communities, Schering will provide patient education materials that will manage an effective transition to HFA inhalers to patients and professionals.

#### 6) Consumer Awareness

In concert with key asthma third party groups such as AAFA, Schering plans to develop a media awareness campaign to roll out following the albuterol CFC ban and continue it throughout the year

- Partnership includes patient and physician tools, media campaign, and call-to-action among CFC users to go visit their physician
- Materials to include Proventil HFA information

#### 7) Patient Education Tools

Materials will feature information on Proventil HFA to ease transition with physicians and patients and will include information about the SP Cares Patient Assistance Program. These materials will be distributed to doctors and patients using our sales representatives, distribution network (including pharmacies), media outreach, and third party groups.

- "Navigating the Transition" Leaflet (Physicians)
  - Created for healthcare providers with HFA Transition Tips
  - Provided to MDs by sales force & offered free via trade media
- "ABCs of HFAs" Brochure (Patients)
  - Brochures in Spanish and English provided through third party groups, pharmacies, and MD offices
  - Offers ways to address HFA with your MD, explains differences between options, includes Proventil HFA information
- "ABCs of HFAs" Press Kit (Media)
  - Developed for media to understand transition in order to write about it; send prior to transition announcement

We will be prepared to begin implementation of our CFC to HFA albuterol transition programs during the months preceding an albuterol CFC ban date. We continue to support a December 31, 2005 effective ban date and we are prepared to initiate our programs accordingly. If the ban date is significantly different than December 2005, we may re-evaluate the scope and timing of these programs.

In conclusion, Schering-Plough supports the FDA's proposed rule to amend section 2.125 by removing paragraph (e)(2)(i), i.e., eliminating the essential use designation for albuterol. We are committed to supporting the FDA and the asthma community in effecting a successful transition.

Please be advised that the material and data contained in this submission are considered to be confidential. The legal protection of such confidential commercial material is claimed under the applicable provisions of 18 U.S.C., Section 1905 or 21 U.S.C., Section 331(j), as well as the FDA Regulations.

Sincerely,



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RG/am

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