Docket No. 2006N-0454
"Use of Ozone-Depleting Substances; Removal of Essential-Use Designations; Public Meeting"

Good Afternoon:

My name is Dr. Rita Jain. I am the Divisional Vice President in charge of Pain, Respiratory, and Metabolic Disease Drug Development at Abbott Laboratories. Abbott welcomes the opportunity to comment on the agency's proposed rule to eliminate the essential use exemptions for the CFC propellants contained in certain oral pressurized metered-dose inhalers -- known as MDIs.

Abbott understands the important environmental issues raised by ozone-depleting substances, and we also recognize the United States' obligations under the Montreal Protocol. We fully support FDA's continuing efforts to phase-out use of ozone-depleting substances (ODSs) in MDIs.

We believe, however, that the effective dates in the proposed rule should be determined on a product-by-product basis to reasonably ensure continued availability of the safe and effective products upon which asthma users currently rely. Specifically, with respect to companies that are diligently developing CFC-free versions of their products, Abbott believes that effective dates should be based on realistic product reformulation efforts and NDA submission and approval timelines. These efforts and timelines need to be worked out between sponsors and FDA.

Our interest in this issue is with Azmacort – our orally inhaled corticosteroid approved for the maintenance treatment of asthma and to reduce or eliminate the need for systemic corticosteroid treatment in asthmatic patients. Azmacort is the only available asthma product offering orally inhaled triamcinolone, and it is the only product in the class supplied with a mouthpiece that includes an attached spacer. Spacers are used to slow the speed at which the medication is ejected, decreasing the amount of medication that deposits in the throat and mouth (which can cause irritation and infection), and increasing the amount of drug that reaches the lungs. Spacers are particularly useful for patients – such as the elderly and children – who may have diminished respiratory flow rates or for whom it is difficult to coordinate depression of the MDI and inhalation of the medication.

One final issue regards the sort of information I am talking about – product development timelines and development discussions with FDA. This is the sort of data that is traditionally guarded by companies (and FDA for that matter) as confidential information not generally subject to public disclosure. Accordingly, Abbott would support FDA creating a mechanism by which such confidential information could be supplied to the agency by individual companies, in order to support product-specific phase-out effective dates, where appropriate.

At Abbott, our prime concern is protecting the interests of patients who depend upon our products. Patients should not be forced to needlessly switch products, provided that sponsors are making a conscientious effort to promptly submit robust applications, consistent with good science and FDA review division discussions and expectations. Accordingly, we request that FDA establish essential-use phase out effective dates consistent with these principles.

Thank You.