

**Wyeth Consumer Healthcare**  
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**Wyeth**

December 4, 2007

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

**RE: Docket 2007N-262/RIN 0910-AF92**  
**Use of Ozone Depleting Substances – Removal of Essential Use Designation**  
**(Epinephrine)**

Dear Sir or Madam:

Wyeth Consumer Healthcare (WCH) is a manufacturer and distributor of Over-The-Counter (OTC) medications, including Primatene® Mist, an inhaled epinephrine product that is propelled by chlorofluorocarbons (CFCs).

While we are disappointed with the Agency's proposal to remove the essential use designation for epinephrine, we acknowledge the Agency's thoughtful review of the information presented at the January 26, 2006 Nonprescription Drugs Advisory Committee (NDAC), and agree that the proposed effective date of December 31, 2010 will be required to provide consumers with sufficient time to transition to other asthma treatments.

In the proposed rule, the Agency has asked for comments on a variety of issues concerning the use of OTC epinephrine inhalers. WCH provided information on those topics at the January 26, 2006 NDAC meeting, and does not have any additional information to address the Agency's questions.

Sincerely,



Lauren Quinn

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