

**Wyeth**

Wyeth Pharmaceuticals

Date: December 10, 2004

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

**Re: Request for Extension of Comment Period: Docket No. 2004D-0378**

Dear Sir/Madam:

Reference is made to Docket No. 2004D-0378 (69 FR 55164-55165). Wyeth Pharmaceuticals is hereby requesting a 30-day extension of the comment period for the ICH draft (step 2) guideline entitled, *ICH S7B: Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals* (dated June 10, 2004). The 30-day extension is requested due to the importance of the subject matter for assessment of safety of pharmaceutical products, and to ensure that any comments submitted on this important topic are based on a thorough assessment of the draft guidance.

Wyeth appreciates the opportunity to comment on the above-mentioned ICH draft guideline, and trusts that the Agency will consider this request.

Sincerely,



Roy J. Baranello, Jr.  
Assistant Vice President,  
Worldwide Regulatory Affairs

2004D-0378

EXT 1