

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

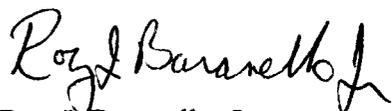
Re: Request for Extension of Comment Period: Docket No. 2004D-0377

Dear Sir/Madam:

Reference is made to Docket No. 2004D-0377 (69 FR 55163-55164). Wyeth Pharmaceuticals is hereby requesting a 30-day extension of the comment period for the ICH draft (step 2) guideline entitled, *ICH E14: Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs* (dated June 10, 2004). The 30-day extension of the comment period is requested due to the importance of the subject matter for assessment of the safety of pharmaceutical products, and to ensure that any comments that are submitted on this important topic are based on a thorough assessment of the draft guidance.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-0377

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