

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

RE: DOCKET NO. 2004D-0377
Comments to Draft Guidance on
E14 Clinical Evaluation of
QT/QTc Interval Prolongation and
Proarrhythmic Potential for
Non-Antiarrhythmic Drugs

Dear Sir or Madame:

As a leader in the discovery, development, manufacture and marketing of medical products, the Johnson & Johnson family of companies is committed to improving health and well being through innovative products and services. We share the Agency's goal of bringing safer and more effective medical products to the market as rapidly as possible. We would like to acknowledge our support of the global initiatives of the International Conference on Harmonisation and we appreciate the opportunity to comment on the Draft Guidance on E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs.

In closing, we would like to thank the Agency in advance for its thoughtful consideration of our recommendations.

Sincerely,

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Bonnie J. Goldmann, MD
Senior Vice President
Global Regulatory Affairs and Quality Assurance

Attachment (1)