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Division of Dockets Management (HFA-305)  
Department of Health and Human Services  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Docket Number 2004D-0377

To Whom It May Concern:

I am writing on behalf of the Duke Clinical Research Institute at Duke University to provide commentary regarding the ICH Draft Guidance on E14 Clinical Evaluation of QT/QTc Interval Prolongation. Specifically, these comments pertain to clarifying language in sections 2.2.1, 2.2.2., and 2.2.3.

In section 2.2.1 - *Collection of Standard 12-Lead Electrocardiograms (ECGs)* - the use of the term “standard 12-lead electrocardiograms” is vague. A suggested alteration of the document language to “high fidelity 12-lead electrocardiogram monitoring devices with a minimum sampling rate of 500 Hz, as defined by the FDA Center for Devices and Radiological Health (CDRH)” clarifies a potential source of confusion. This suggested change applies to the title of section 2.2.2., *Assessment of Standard 12-Lead ECGs*.

In section 2.2.3 – *Ambulatory ECG Monitoring* – the use of the term “ambulatory ECG monitors” is vague. A suggested change in this section is to define ambulatory ECG monitors as “ambulatory ECG monitors with non-high fidelity ECG instruments (maintaining a sampling rate less than 500 Hz)”. This clarifying statement would be included throughout section 2.2.3. to eliminate confusion regarding the devices being employed.

Thank you for the opportunity to provide guidance during the draft period of the E14 document. Please contact me with any questions or comments that you have regarding this topic.

Sincerely,  
Dr. Chris Cabell, M.D.