



August 21, 2006

Division of Dockets Management (HFA-305)  
Docket No. 2006D-0191  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

To Whom It May Concern:

Alquest, Inc. would first like to thank CRDH and the FDA for their work in providing the *Draft Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials*. This is a critical step in the transition toward the use of Bayesian statistics in medical device trials. Bayesian methods present as the natural statistical method in the development of medical devices. It lends itself as a fit that may assist in the efficient production of safe and effective devices.

Overall, this is an easily understood document that exposes non-statistical team members to the background of Bayesian statistics. In some places it does read like a statistics lesson. However, it is understood that some assumption of background statistical knowledge must be made. Perhaps that assumption could be stated.

There were a couple of points on which we would like clarification. The effective use of Bayesian methods relies on the employment of "good priors". Therefore it is imperative that a definition of "good priors" be provided. It may also be helpful to provide a risk/benefit analysis to choosing "not so good priors."

In section 3.4 the FDA recommends sponsors meet with the FDA to discuss experimental design, models and acceptable prior information. In what forum will the FDA participate in planning Bayesian trials? What type of meetings will these be? Will these be binding or non-binding? In agreement meetings will the FDA be permitted to reject a Bayesian approach and require a Frequentist analysis?

In section 3.9 a change in device labeling is noted as a potential difficulty in Bayesian approaches. How might device labels differ for Bayesian designs? Perhaps examples could be provided.

We look forward to the future of Bayesian statistics in medical device trials. Should you have questions regarding our thoughts, you can contact me at by email at [alobbestael@alquest.com](mailto:alobbestael@alquest.com) or by phone at 763-287-3830.

For and in behalf of Alquest, Inc.,

A handwritten signature in black ink, appearing to read 'A. Lobbestael', written in a cursive style.

Aaron Lobbestael  
Statistical Consultant