

## Meeting Summary

**Date:** June 14, 2010

**Time:** 11:00 AM – 12:00 PM

**From:** Cherie Ward-Peralta

**To:** STN 125325/0

**Re:** OOS Investigation for Kamada Alpha-1-Proteinase Inhibitor (Human)

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### **FDA Participants:**

Cherie Ward-Peralta, Ewa Marszal, Dorothy Scott, Dave Doleski, and Stan Lin

### **Background:**

The sponsor has submitted an Original BLA submission for Alpha-1-Proteinase Inhibitor (Human), intravenous for chronic augmentation and maintenance therapy in individuals with congenital deficiency of alpha-1-proteinase inhibitor (A1-PI) and clinical evidence of emphysema. During the pre-license inspection, we requested for the sponsor to define a rigid retesting vial process that specifies a number of testing vials that should pass.

### **Discussion:**

The review committee requested to discuss the performance of the out of specification (OOS) Investigation for Alpha-1-Proteinase Inhibitor (Human). Specifically, we discussed whether to allow Kamada to -----(b)(4)-----

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DMPQ Reviewer stated the manufactures should not be testing a lot into compliance. That is why rigid procedures must be established prospectively. Lead Reviewer confirmed the sponsor's SOPP does not allow testing a lot into compliance.

Statistical Reviewer suggested reviewing the lot acceptance testing procedure to understand better their SOP for OOS Investigations.

The review committee agreed to the suggestion, but we also need to discuss what would be the allowable number of samples to be retested for the OOS investigation. The Statistician Reviewer stated the ----- (b)(4) ----- does allow to perform the Grubb Test. Therefore, all participants agreed that Kamada's proposal for handling any potential OOS results would be acceptable.

Based on our experience with regulated industry, we decided that OOS situations are infrequent events. Therefore, ----- (b)(4) -----  
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The review committee agreed ----- (b)(4) -----  
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End of Meeting

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