



## Filing Meeting Summary

**Date:** May 28, 2015  
**From:** Christopher Hooban, CBER/OBRR  
**To:** 125587/0  
**Subject:** Immune Globulin Intravenous (Human), 10%

---

### **CBER Participants:**

Cagungun, Nannette  
Campbell, Karen  
Chazin, Howard  
Deng, Lu  
Glen, Jacqueline  
Hooban, Christopher  
Hu, Jiang (Jessica)  
Kaur, Simleen  
Kennedy, Michael  
Landow, Laurence  
Lynch, Christian  
McCormick, William  
McDowell, Erin  
Melhem, Randa  
Mintz, Paul  
Paul, Wendy  
Staschen, Carl-Michael  
Wang, Yongang

### **Discussion:**

- No RTF. The BLA can be filed.
- No deficiencies were identified.
- A concern was brought up by Laurence Landow with respect to the terminology used to describe one of the indications (Primary Immune Thrombocytopenia (within the NGAM-02 final study report) v. Chronic Thrombocytopenic Purpura in Adults (within the BLA cover letter and Full Prescribing Information)). An information request (IR) will be submitted to the sponsor to provide clarification and update documents (i.e., package insert and cover letter) via an amendment to the submission.
- Inspection of the French facility in Lingolsheim is planned for OCT 2015.

### **Action Items:**

- Chris Hooban will draft and submit an IR concerning the noted differences in terminology used to describe the condition under study. The IR will request clarification and modification of appropriate documents.
- Reviewers will provide an email to Chris Hooban confirming that the submission can be filed.