

**From:** [Wood, Lorraine](#)  
**To:** [Ammons, Stanley](#)  
**Subject:** Information Request for BLA 125612: Sterility Test Qualification  
**Date:** Friday, September 23, 2016 12:34:00 PM  
**Importance:** High

---

Dear Mr. Ammons,

We are reviewing your submission for BLA 125612 and we request the following information to continue our review:

### **Sterility Test Qualification**

1. Please provide (b) (4) results for the B&F test performed on Human Fibrinogen DP, to confirm the inoculated microorganism counts were less than (b) (4) .
2. In addition to the (b) (4) indicator microorganisms tested in the B&F qualification, CBER requests at least two known environment isolates found in your Vienna, Austria facility be tested to determine if your DP has inhibitory properties preventing their detection.
3. According to document 001VAL106FC 34x/00 – “Test for Sterility by (b) (4) on Fibrinogen acc. (b) (4)”, sterility test qualification was performed by comparing test results with their representative positive control. However, your negative control results for this assay were omitted. Please submit your negative control results.

Please respond to this request by October 7, 2016.

Thank you

*Lorraine D Wood, MS, MLS(ASCP)<sup>CM</sup>*  
Regulatory Project Manager  
Food & Drug Administration  
Center for Biologics Evaluation and Research  
Office of Blood Research and Review  
WO71-4205  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
Phone# 240-402-8439  
Mobile# 240-762-2283

**THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.**