

## Dehdashti, Seameen (Jean)

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**From:** Dehdashti, Seameen (Jean)  
**Sent:** Friday, November 23, 2018 6:10 PM  
**To:** 'BDV (Barbara Davies)'  
**Cc:** Dehdashti, Seameen (Jean)  
**Subject:** FDA Information Request - CMC (Facility): BLA 125671/0

Dear Barbara,

We are reviewing your BLA submission for Antihemophilic Factor (Recombinant), GlycoPEGylated, turoctocog alfa pegol (STN 125671), and have the following information request (IR), outlined below in **bold text**. Please send us your response by close of business, Friday, November 30, 2018.

### **FDA Information Request (IR) – CMC (Facility)**

Please provide the following related to QC lab at the (b) (4)

- 1. A list of major testing instruments and respective documentation (SOPs, etc.), which describes (regulates) the equipment qualification, calibration and maintenance.**
- 2. An SOP describing procedure(s) for buffers and reagents preparation.**

Please confirm receipt of this communication, and do not hesitate to contact me, should you have any questions and/or concerns.

Warm regards,

**Jean Dehdashti, MSc, RAC**  
**Regulatory Project Manager**

**Center for Biologics and Evaluation Office**  
**of Tissues and Advanced Therapies**  
**U.S. Food and Drug Administration**  
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