

## Dehdashti, Seameen (Jean)

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**From:** Dehdashti, Seameen (Jean)  
**Sent:** Friday, November 30, 2018 5:06 PM  
**To:** 'BDV (Barbara Davies)'  
**Cc:** Dehdashti, Seameen (Jean)  
**Subject:** FDA Information Request - CMC: 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, Tuesday, January 15, 2019.

**FDA Information Request (IR) – CMC:**

**CBER requests the bioburden testing be requalified with a sample size of (b) (4), as per (b) (4) sample size requirements, unless smaller amounts are justified due to lot size.**

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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