

## Dehdashti, Seameen (Jean)

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**From:** Dehdashti, Seameen (Jean)  
**Sent:** Monday, December 03, 2018 6:32 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, Monday, December 10, 2018.

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

**Please provide an SOP(s) describing procedures for buffers and reagents preparation used in production of the Drug Substance at the (b) (4) facility.**

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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