

## Dehdashti, Seameen (Jean)

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**From:** Dehdashti, Seameen (Jean)  
**Sent:** Thursday, January 10, 2019 9:43 AM  
**To:** 'BDV (Barbara Davies)'  
**Cc:** Dehdashti, Seameen (Jean)  
**Subject:** FDA Information Request - CMC: BLA 125671/0

**Importance:** High

Good morning 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, Wednesday, January 16, 2019.

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

In sections **3.2.P.5.4 Batch analyses** and **3.2.P.8 Stability**, you provided release and stability data for the drug product of nominal dosage strengths of 500, 1000, 2000, and 3000 IU. However, you did not provide any data for the dosage strength of 1500 IU. Although you followed the (b) (4) approach in your validation strategy, we find the data at the lower end insufficient considering that only (b) (4) of 1000 IU was manufactured at commercial scale and only 12-month stability data are currently available for PPQ lots at long-term storage conditions. Therefore, please provide additional experimental evidence to support the (b) (4) approach. For example, please provide comparative trend analyses of stability data from accelerated stability study (b) (4) for critical stability-indicating parameters for all available dosage strengths.

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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