

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Wednesday, January 09, 2019 3:12 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request - CMC: BLA 125671/0

Importance: High

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, Wednesday, January 23, 2019.

FDA Information Request (IR) – CMC:

The following IR is regarding the identity/purity by (b) (4) method for turoctocog alfa pegol (b) (4) drug product (STN: 125671):

In the robustness study (b) (4) : Validation of analytical procedure (b) (4) identity and purity by (b) (4), you have demonstrated that (b) (4) temperature at either (b) (4) has a significant impact on the PEGylation profile and (b) (4) in the (b) (4) samples, but still keep the (b) (4) temperature at (b) (4) unchanged in your SOP with unclear (b) (4) temperature adjustment information. Please narrow the (b) (4) temperature range in your SOP based on your robustness study results, or provide clearer information and justification on the (b) (4) temperature adjusting procedure in the SOP, and provide the updated version of the SOP (b) (4) within 14 days of receipt of this IR.

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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