

Dehdashti, Seameen (Jean)

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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