

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Monday, December 17, 2018 3:18 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, Thursday, December 27, 2018.

FDA Information Request (IR) – CMC:

We reviewed your responses to our November 26, 2018 information request (IR), which were submitted on December 11, 2018 as Amendment 48 to the original BLA, and found your responses to the following questions to be inadequate.

Acceptance criterion for (b) (4) in Drug Product

We still disagree with your approach to establish the acceptance criterion for (b) (4) in the Drug Product based on the acceptance criterion for the Drug substance and (b) (4) of the Drug Product manufacturing and handling processes. Your data does not show consistent increase of (b) (4) level in Drug Product over the level in Drug Substance. As such, unless proposed acceptance criterion for Drug Product is based on the level of (b) (4) in the corresponding Drug Substance lot, your approach is not appropriate. Please justify and establish the acceptance criterion for (b) (4) in the Drug Product based on statistical analysis of release testing data. Based on the data provided in Amendment 48, (b) (4) Release (b) (4) Shelf-life) appear to be justified acceptance criteria for this parameter.

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

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of Tissues and Advanced Therapies
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