

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Friday, September 21, 2018 8:33 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request (IR): 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 Friday, October 05, 2018. If you feel that you will not be able to meet this timeline, please propose the date by which you can provide the requested data.

FDA Information Request (IR):

- 1. With reference to sections 3.2.P.2.4 and 3.2.P.5.5-3.5, in your assessment of leachables in the lyophilized Drug Product (DP), you explained that you had not assessed elemental compounds, e.g., metals, because you did not find such compounds (i) from the rubber stopper of the container closure system (extractables study); and (ii) “in other approved lyophilized hemophilia drug products using the same combination of vial and rubber stopper”. However, elemental compounds can come from other parts of the manufacturing process, which is different for different antihemophilic factor products, as well as the glass vial itself. Therefore, please provide an assessment of elemental impurities in the DP, similar to that conducted for organic leachables, i.e., under real-time storage conditions at multiple time-points throughout the product shelf-life.**
- 2. Please submit study reports for the analysis of leachables in the DP (described in section 3.2.P.2.4). In addition, please include description of the analytical procedures used in these studies, with assessments of recoveries of model compounds in during (b) (4) .**

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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