

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Friday, September 28, 2018 12:06 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 Wednesday, October 10, 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. Please submit a list of the analytical tests used at the (b) (4) for the control of the following production materials:
 - a. Raw materials
 - b. In-process intermediates
 - c. Bulk Drug Substance

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

Tel: 240-402-9146

Seameen.Dehdashti@fda.hhs.gov



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.