

From: [Dehdashti, Seameen \(Jean\)](#)
To: ["BDV \(Barbara Davies\)"](#)
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR): BLA 125671/0
Date: Tuesday, July 24, 2018 4:59:29 PM
Attachments: [image004.png](#)

Dear Barbara,

Reference is made to Novo Nordisk, Inc., original BLA 125671 submission, dated February 27, 2018. We are reviewing your BLA submission for Antihemophilic factor, GlycoPEGylated (STN125671) and have the following information request (IR), outlined in **bold text** below. Please provide your response by Tuesday, August 07, 2018.

FDA IR:

- 1) CBER expects environmental isolates to be qualified as part of your method qualification to ensure they can also be detected in addition to the indicated (b) (4) microorganism, which are generally representative of potential bioburden contaminants. Therefore, CBER requests known environmental isolates from the Novo Nordisk A/S, (b) (4) facility be tested for (b) (4) drug product matrixes qualification of the sterility and bioburden test methods and submitted to CBER for continual review.**

- 2) Please provide conformance lot numbers, (b) (4) of positive control (b) (4), and results for negative controls used in the sterility qualification study (document ID 003516139).**

- 3) Please provide rationale for selecting (b) (4) drug product. CBER requests qualifying endotoxin method using a (b) (4) below (b) (4) and choosing a (b) (4) that provides optimal Product Positive Control (PPC) % recoveries (e.g., closest to (b) (4)). Please include any preliminary interference testing results, if available.**

Please confirm receipt of my e-mail, 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



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