

Record of Telecon on IR, January 4, 2013 - Novoeight

Date: 4-Jan-2013

To: STN 125466/0 Antihemophilic Factor (Recombinant), Plasma/Albumin Free [NovoEight]

From: Leigh Pracht

Subject: Request for additional facility and manufacturing detail.

Discussion Points:

On December 17, 2012, the following request was sent to Novo Nordisk:

1. In the BLA submission (Manufacturer section), you have provided a general overview of the facilities as relates to production of NovoEight. Please provide in a Table format detailed description of the operations performed in each of the Buildings/Facilities for both Novo Nordisk ---(b)(4)---.

The applicant replied to the request by submitting the same table that had been submitted in the original application. Randa Melham, the DMPQ reviewer, requested I call Cindy Cao at Novo Nordisk and explain that more detailed information is required.

Novo should explain what types of testing and specific activities taking place at there manufacturing sites. For example, what does “visual inspection” exactly mean?

This request is being made to facilitate DMPQ in scheduling pre-licensing inspections.

We requested the revised table be received by the FDA NLT 14-Jan-13.

END

Page Last Updated: 11/15/2013

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