

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125398/0 Office: OBRR

Product:
Coagulation Factor XIII A Subunit (Recombinant)

Applicant:
Novo Nordisk Inc.

Telecon Date/Time: 30-May-2013 09:30 AM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):
1. Information Request

Author: JIAHUA QIAN

Telecon Summary:
To discuss issues related to Novo Nordisk's facility in (b) (4), one of the manufacturing sites for the product.

FDA Participants: Destry Sillivan and Zuben Sauna

Non-FDA Participants: Robert Fisher

Telecon Body:

FDA requested a teleconference to discuss issues related to Novo Nordisk's facility at (b) (4).

FDA stated that most complete response review issues appear to have been satisfactorily resolved, but that final determination will be made at the conclusion of the review cycle. The response to the visual inspection question (CR Letter #15) has not been adequately addressed in that it still lacks a detailed description of the program and how that program has been validated. For instance:

- You list two defect sets; one for lyophilized products, one for unknown products that are potentially both used for qualification. Please describe exactly how and why these defect sets are utilized. Note also that the lyophilized product defect set is composed of far more defects that is appropriate; defect sets should be composed of approximately 90% good articles.
- You have not provided evidence that you have actually qualified your inspectors for this product. Please provide your inspection qualification data.

- Your basis for your AQL inspection has not been provided. Please provide all characteristics of this inspection. Please also describe under what conditions you will proceed to a 100% re-inspection of a lot that fails initial inspection.
- Please provide lot failure limits for critical and major defects.

There is added concern with respect to this issue as FDA carried out an inspection of Novo Nordisk's (b) (4) facility from (b) (4). The issues related to the visual inspection were reported in the FDA Form 483, item number 12 to 19. The issues identified here must be satisfied as well.

Novo Nordisk committed to the following:

1. Responding to FDA's written information request by Friday, May 31st 2013.
2. Providing complete details of the visual inspection program by Friday, June 7th 2013.
3. Novo Nordisk's responses to deficiencies identified in the Form 483 following FDA's inspection of the (b) (4) facility will be submitted as an amendment to this BLA