



Official Meeting Summary

Meeting ID #: CRMTS #8352
Application type and number: BL 125398/0
Product name: Factor XIII A Subunit (Recombinant)
Applicant: Novo Nordisk Inc. (Novo Nordisk)
Meeting type: Type C
Meeting category: BLA, Other
Meeting date & time: March 14, 2012, 11 a.m. – 11:55 a.m.
Meeting format: Face-to-face
Meeting Chair/Leader: Mahmood Farshid, Ph.D.
Meeting Recorder: Debbie Cordaro

FDA Attendees:

Roman Drews, Ph.D., Chemist, Division of Hematology, OBRR
Timothy Lee, Ph.D., Acting Chief, Laboratory of Hemostasis, Division of Hematology, OBRR
Mahmood Farshid, Ph.D., Deputy Director, Division of Hematology, OBRR
Debbie Cordaro, Regulatory Project Manager, Division of Blood Applications, OBRR
CDR Destry Sullivan, Senior Regulatory Review Officer, Division Manufacturing and Product Quality, OCBQ
Grace Deneke, Consumer Safety Officer, Division Manufacturing and Product Quality, OCBQ

Novo Nordisk Inc. Attendees:

Novo Nordisk A/S (Denmark):

Henrik Kim Nielsen, Corporate Vice President, Regulatory Affairs Hemophilia Projects
Andrew Chang, Executive Director, Regulatory Affairs, Hemostasis
Jesper Johansen, Senior CMC Project Manager
Kim Jacobsen, Project Vice President, Hemostasis Management
Lene Hoerlyck, Senior Project Manager, CMC Biopharm Analysis & Formulation
Susanne Lund Olsen, Senior Project Manager, Regulatory Affairs
Arne Agerlin Olsen, Principal Scientist, Product Supply
Torben Storgaard Guldberg, Director
Birgit Schultz, Corporate Vice President
Thomas Budde Hansen, Principal Scientist

Novo Nordisk Inc. (Princeton, NJ):

Robert Fischer, Senior Director, Regulatory Affairs
Lewis Pollack, Senior Director, Regulatory Affairs

Background and Objectives:

Novo Nordisk Inc. (Novo Nordisk) submitted a biologics license application (BLA) for this product on February 23, 2011. FDA conducted an inspection of two manufacturing facilities (Bagsvaerd (b) (4)). At the close of the inspection on (b) (4), two separate Form FDA 483s were issued. On December 23, 2011, FDA issued a complete response letter that included 29 specific issues to be addressed.

Novo Nordisk submitted a meeting request on January 9, 2012, to discuss CR issues related to:

- Outstanding Issues from the Pre-License Inspection
- Supplemental Process Validation
- Manufacturing and Inspection Issues
- Lyophilization Qualification

On January 18, 2012, a teleconference was held with representatives from the Division of Manufacturing and Product Quality, Office of Compliance and Biologics Quality, and the Division of Hematology, Office of Blood Research and Review to specifically discuss Novo Nordisk's concerns about Issue 1, the pre-approval inspection.

For this meeting, Novo Nordisk submitted pre-meeting materials including 19 questions on February 15, 2012. FDA provided written responses to Novo Nordisk's questions on March 8, 2012. After reviewing the responses, Novo Nordisk, on March 13, 2012, notified FDA that for the scheduled meeting, they intend to discuss only question numbers 8, 9, 10, 11, 16, and 18 of the CR letter.

It should be noted that this meeting brought to 35, the number of interactions (including teleconferences, outgoing information requests, incoming responses, etc.) with the sponsor since the submission of the BLA.

Discussion:

Supplemental Process Validation (Item #2 from Complete Response letter):

Applicant Question 1:

For Item 2a in the Complete Response Letter, the Agency has requested (b) (4) for chromatography columns (b) (4) from the three PV runs and (b) (4) (b) (4) for the respective columns. In Section [10.1.1.1](#), all of the requested information is presented.

Does the Agency agree that the presented data are sufficient to address the deficiency?

FDA Response to Question 1:

The presented data appear to be sufficient. However, the adequacy of the response to Question 2a will be evaluated during the review of Novo Nordisk's official response to the CR letter.

Additional discussion:

This question was not discussed during this meeting.

Applicant Question 2:

For Item 2b in the Complete Response Letter, the Agency recommended to include parameters (b) (4) [REDACTED] (b) (4) in the supplementary in-process control testing outlined in Amendment # 19 (Table 5 on Page 9 of 12). Novo Nordisk has conducted some preliminary testing with the current analytical method for (b) (4) [REDACTED], and the data suggests that it will be possible to test in-process (b) (4) [REDACTED] with the existing method. In-process samples from the supplementary process validation batches will be tested and results of (b) (4) [REDACTED] (b) (4) [REDACTED] (b) (4) will be included in the response to the Complete Response letter.

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 2:

The presented approach is acceptable but the adequacy of the response to Question 2b will be evaluated during the review of Novo Nordisk's official response to the CR letter.

Additional discussion:

This question was not discussed during this meeting.

Applicant Question 3:

For Item 2c in the Complete Response Letter, the Agency has requested side-by-side comparison of the manufacturing runs for the PV and clinical batches. All of the requested information is presented in Section [10.1.1.3](#).

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 3:

The presented data appear to be acceptable. However, the adequacy of the response to Question 2c will be evaluated during the review of Novo Nordisk's official response to the CR letter.

Additional discussion:

This question was not discussed during this meeting.

Applicant Question 4:

For Item 2d in the Complete Response Letter, the Agency has requested the justification of the change in the (b) (4) criterion and a risk assessment for the potential impact of the proposed change on the quality attributes of rFXIII BDS. All the requested information is presented in Section [10.1.1.4](#).

Does the Agency agree that the presented information is sufficient to address the Deficiency?

FDA Response to Question 4:

The presented data appear to be acceptable. However, the adequacy of the response to Question 2d will be evaluated during the review of Novo Nordisk's official response to the CR letter.

Additional discussion:

This question was not discussed during this meeting.

Applicant Question 5:

For Item 2e in the Complete Response Letter, the Agency has recommended to include (b) (4) in the monitoring of manufacturing steps (b) (4). The data for these parameters are presented in Section [10.1.1.5](#).

Does the Agency agree that the presented data are sufficient to address the deficiency?

FDA Response to Question 5:

The presented data appear to be acceptable. However, the adequacy of the response to Question 2e will be evaluated during the review of Novo Nordisk's official response to the CR letter.

Additional discussion:

This question was not discussed during this meeting.

Applicant Question 6:

For Item 2f in the Complete Response Letter, the Agency has requested the confirmation of the prerequisite limit for manufacturing step (b) (4). In Section [10.1.1.6](#), Novo Nordisk confirms the prerequisite limit and presents the data.

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 6:

The provided information is adequate.

Additional discussion:

This question was not discussed during this meeting.

Applicant Question 7:

For Item 2g in the Complete Response Letter, the Agency has requested a summary of the investigation of the deviations that led to process failure. In Section [10.1.1.7](#), the requested information is presented.

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 7:

The presented data appear to be acceptable. However, the adequacy of the response to Question 2g will be evaluated during the review of Novo Nordisk's official response to the CR letter.

Additional discussion:

This question was not discussed during this meeting.

9.2, Manufacturing and Inspection Issues (Item #3-10 and 14-15 from Complete Response Letter):

Applicant Question 8:

For Item 3 in the Complete Response Letter, the Agency has requested to include acceptance limits for additional in-process control parameters. (b) (4) were not critical in-process tests during the Propagation, Fermentation and Initial recovery, and were monitored with alert limits. However, it was not possible to determine parameter (b) (4) at step (b) (4). The parameter was determined at step (b) (4) as non-critical in-process test which is trended. The details of the information are presented in Section [10.2.1](#).

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 8:

With regards to Questions 3a and 3b in the CR letter:

No, the submitted information is not sufficient to address the deficiency communicated by the Agency in Question 3. Since (b) (4) is not controlled for manufacturing Step (b) (4) the following in-process control parameters should be considered as critical for the control strategy of the fermentation process:

(b) (4)

Furthermore, they can have significant effect on the performance of downstream process and quality attributes of the final product. Therefore, the Agency reiterates its request to include Acceptance Limits for these three in-process control parameters.

With regards to Question 3c in the CR letter, please establish Alert Limits for the (b) (4) (b) (4) at manufacturing Step (b) (4)

Additional discussion:

Novo Nordisk agreed with FDA's request to introduce Acceptance Limits for the following in-process control parameters: (b) (4)

(b) (4) Also, Novo Nordisk agreed to add Alert Limits for the (b) (4) at manufacturing Step (b) (4)

Applicant Question 9:

For Item 4 in the Complete Response Letter, the Agency has requested Novo Nordisk to include acceptance limits for additional in-process control parameters for Recovery and Purification. The detailed control strategy (including alert limits for the requested parameters for steps (b) (4)) are presented in Section [10.2.2](#).

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 9:

No, the submitted information is not sufficient to address the deficiency outlined in Question 4. Therefore, the Agency reiterates our request to Novo Nordisk to include in the control strategy for *Recovery and Purification* (Steps (b) (4)) the Acceptance Limits for the following in-process control parameters:

- (b) (4)

The outlined in-process control parameters should be considered as critical because deviation from their respective limits or acceptance criteria can significantly impact the performance of the purification process and quality attributes of the final product.

The Agency agrees with the proposed control strategy for the following in-process controls:

- (b) (4)

Additional discussion for Question 9:

In general, Novo Nordisk agreed with the control strategy outlined by the FDA for *Recovery and Purification* (Steps (b) (4)) and proposed the following (see attachment 1 for details):

- (b) (4)
 - (b) (4)
- ”

FDA stated that the proposal will be reviewed and assessed upon receiving it in the official response to the Complete Response (CR) letter. FDA added that Novo Nordisk should provide justification(s) to support the combination of Steps (b) (4) as one (b) (4) for an in-process control parameter. Furthermore, FDA pointed out that more detailed description should be added to the currently proposed acceptance criterion for (b) (4)

Applicant Question 10:

For Item 5 in the Complete Response Letter, the Agency has recommended to include a specification for potency and (b) (4) for purity measurement in the release specification of the (b) (4) Final Drug product. Novo Nordisk has proposed release limits of the two specifications in Section [10.2.3](#).

Does the Agency agree that the proposed limits are acceptable for the two recommended specifications?

FDA Response to Question 10:

In general, the provided data are acceptable. However, the adequacy of the response, including the proposed specification limits, will be evaluated during the review of Novo Nordisk’s official response to the CR letter.

Please retain *Specific Bioactivity* and include (b) (4) as specifications for the release of the Final Drug Product.

In addition, with reference to your response to Question 5b, please describe the calculation of *Purity* and *Impurities* for the release of the Final Drug Product, specifically, please indicate whether (b) (4) are integrated for these calculations.

Additional discussion:

Novo Nordisk agreed to retain the *Specific Bioactivity* specification for the release of Final Drug Product (FDP).

With regard to FDA's request to include (b) (4) as a release specification for FDP, Novo Nordisk stated that the data demonstrated effective removal of (b) (4). Therefore, instead of having it as an FDP release specification, Novo Nordisk proposed to include (b) (4) as an alert limit at Step (b) (4) and to add a second alert limit at Step (b) (4) of the drug substance manufacturing process. Failure to meet these two alert limits would trigger an immediate investigation.

FDA stated that the adequacy of the proposed control strategy for (b) (4) will be determined when Novo Nordisk submits the official response to the CR letter. In addition, FDA requested that data from a spiking study, conducted in the course of process development, in which (b) (4) has been demonstrated by Step (b) (4) be submitted for review.

Novo Nordisk proposed a plan to include (b) (4) in the calculation of Purity and Impurities for the release of FDP. FDA agreed with this approach.

Applicant Question 11:

For Item 6 in the Complete Response Letter, the Agency has recommended to include contents of L-Histidine and Polysorbate 20 in the release specification of the Final Drug Product. Novo Nordisk acknowledges the Agency's recommendation. However, analytical testing of the excipients Histidine and Polysorbate 20 is not considered to be necessary as no change is expected for these excipients during processing of the drug product. In addition, correct quality and content of excipients is assured by applied GMP procedures. Furthermore, the robustness of the formulation with respect to changes in the concentration of these excipients has been confirmed. The proposed specification for rFXIII drug product complies with ICH Q6B assuring the quality, purity and potency of the product.

Details of the control strategy of the excipients are presented in Section [10.2.4](#).

Does the Agency agree that the current control strategy for the two excipients is adequate, therefore the contents of the two excipients are not required to be included in the Final Drug Product Specification?

FDA Response to Question 11:

FDA agrees that the outlined control strategy for Histidine is acceptable. However, please include the *Level of Polysorbate 20* as a specification for the release of the Final Drug Product.

Additional discussion:

Novo Nordisk inquired why there is a need to include testing for Polysorbate 20 to the FDP specification whereas Histidine level could be omitted. FDA pointed out that the measurement of pH in the FDP specification is a surrogate for Histidine level. However, there is no surrogate controls for Polysorbate 20 in the FDP specifications, and therefore, testing will be needed.

Novo Nordisk confirmed that, following FDA's request, Novo Nordisk will add *Level of Polysorbate 20* as a release specification of FDP.

Furthermore, FDA agreed to Novo Nordisk's proposal to submit to the BLA an interim specification limit for Polysorbate 20, followed by final specification limit and supporting validation data, 3 months before the action due date of the response to the CR letter.

Applicant Question 12:

For Item 7 in the Complete Response Letter, the Agency has recommended to include the analysis of (b) (4) as part of the assessment of clearance for process related impurities related to the yeast extract used in the cell culture media. As described in Section [10.2.5](#), preliminary data of analysis indicate that the level of (b) (4) is negligible after the (b) (4) (b) (4). In addition, the clearance of (b) (4) will be evaluated in a study, where rFXIII in-process samples are analysed. The results will be included in the assessment of clearance for impurities related to the fermentation process. Novo Nordisk considers it is not necessary to include the analysis of (b) (4) as part of the routine assessment of clearance for process related impurities.

Does the Agency agree that the analysis of (b) (4) as part of the routine assessment of clearance for process related impurities related to the yeast extract used in the cell culture media is not required?

FDA Response to Question 12:

FDA cannot respond to your question at this time because the data demonstrating clearance of (b) (4) have not been submitted for our review.

Additional discussion:

This question was not discussed during this meeting.

Applicant Question 13:

For Item 8 in the Complete Response Letter, the Agency has requested manufacturing information of the Novo Nordisk rFXIII A2 BDS batches. The requested information is included in Section [10.2.6](#).

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 13:

Yes, FDA agrees.

Additional discussion:

This question was not discussed during this meeting.

Applicant Question 14:

For Item 9 in the Complete Response Letter, the Agency has some concerns over a (b) (4) (b) (4) of (b) (4) with the submitted SST sample using method M003.

Detailed clarification and Novo Nordisk experience on the SST samples are included in Section [10.2.7](#).

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 14:

The data presented regarding stability of the (b) (4) from reconstituted SST sample as submitted is not consistent with experience in CBER labs. Resubmission of new SST sample for further evaluation should be anticipated.

Additional discussion:

Novo Nordisk will submit a new standard for M0003. FDA recommended a telecon before beginning the qualification of the new standard.

Applicant Question 15:

For Item 10 in the Complete Response Letter, the Agency has requested information on the effect of (b) (4) (b) (4). As described in Section [10.2.8](#), study data regarding dilution in (b) (4)) vs. water demonstrate that (b) (4) (b) (4) does not (b) (4)

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 15:

The presented data appear to be acceptable. However, the adequacy of the response will be evaluated during the review of Novo Nordisk's official response to the CR letter.

Additional discussion:

This question was not discussed during this meeting.

Applicant Question 16:

For Item 14 in the Complete Response Letter, the Agency has requested detailed descriptions of all connections between rFXIII process equipment. A detailed description of all connections and bioburden analysis data are presented in Section [10.2.9](#).

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 16:

With respect to CR item 14b, we agree that the (b) (4) step appears to be conducted in a (b) (4) system. Therefore, performance of your (b) (4) process in a “(b) (4)” environment may be appropriate.

For other aspects of your manufacturing process, you still have not provided sufficiently detailed information regarding how your equipment is assembled prior to use, and at what condition it is held post cleaning, thus for us to make a determination regarding the system as (b) (4). However, since you state in Table 22 that you only intend to claim that the system(s) is/are (b) (4) with respect to (b) (4), you no longer need to provide validation data that demonstrates that the respective systems are in fact (b) (4) except for (b) (4). With respect to that column, use of sanitization procedures coupled with a cleaning validation that has to date been viewed as inappropriate and/or not validated do not support your claim that this system is (b) (4).

Please also consider that information you have provided as part of your meeting package is inadequate and it does not provide an assessment or justification for the selected manufacturing processes, considering the in-process bioburden data. In-process bioburden obtained from only one processing step cannot satisfy this question.

Additional discussion:

FDA stated bioburden testing should be established at the critical process steps to ensure adequate control of FXIII manufacturing process. Novo Nordisk has identified all the manufacturing steps to indicate if they are (b) (4), and clarified that not all of the processes are (b) (4) certain steps. However, there are not enough details describing how all connections are made between equipment. During the recent inspection, FDA noted that some of Novo Nordisk’s SOPs and Batch Instructions lacked sufficient details in order for the operators to follow the correct procedures. Novo Nordisk should evaluate the instructions for each process step, and then submit a detailed description of each manufacturing step to FDA. Additionally, please revise the batch record to ensure that complete manufacturing instructions are provided in that document.

Novo Nordisk referred to its presentation to depict the critical in-process tests and the accepted limits for bioburden and endotoxin (attachment 1).

Any decision to lower the bioburden acceptable limits should be based on the manufacturing process. For all steps, Novo Nordisk will submit more detailed data on the connections, the type of connections, and how the processes are performed.

FDA will evaluate the in-process bioburden data when it is submitted in the response to the CR letter.

Applicant Question 17:

For Item 15 in the Complete Response Letter, the Agency has requested additional information on the 100% Visual Inspection Program for rFXIII. The requested information is presented in Section [10.2.10](#).

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 17:

The final review of the visual inspection issues will be made when you submit your complete response. However, please consider the following:

- a. What color is your normal lyophilization cake? There should be a category for this under your section entitled, “Freeze drying cake” so as to ensure that cake color is considered.
- b. Your defect set does not account for particulates adhered to the inside of the vial.
- c. A defect set should often include more than one defect of the same type, when a defect may manifest in varying degree for detection. For instance, particulates can be very large, or barely visible. Your defect set, as described, includes only one particulate of an undefined size and therefore does not span a range of potential particulate sizes that could be encountered, to include particulates that are both of large and barely visible sizes.
- d. Please submit documents that describe your entire visual inspection program, to include data that demonstrates that you have validated the program.

Additional discussion:

This question was not discussed during this meeting.

9.3 Lyophilization Qualification (Item #16-17 from Complete Response Letter)

Applicant Question 18:

For Item 16 in the Complete Response Letter, the Agency has recommended to include more samples taken from all shelves from (b) (4) production lyophilizers for Lyophilization qualification. As described in Section [10.3.1](#), Novo Nordisk agrees to perform a study to include more sampling from all (b) (4) shelves during manufacturing of the batch for process confirmation employing drug substance manufactured in the Supplementary Process Validation on Purification. The study protocol is included in the meeting package ([Appendix B](#)). A final study report for (b) (4) lyophilizer will be submitted in the complete response to the CR Letter. The (b) (4) lyophilizer will be similarly qualified and taken into use when necessary to meet market demand.

Does the Agency agree that the presented information and the proposed study protocol and validation approach are sufficient to address the deficiency on lyophilization qualification?

FDA Response to Question 18:

With respect to your amended lyophilization sampling plan, we reiterate our comments made on February 29, 2012 to Mr. Robert Fischer via teleconference. Your sampling plan is acceptable provided you include sampling of alternate locations outside of the selected (b) (4) for critical lyophilization parameters such as cake appearance, residual moisture, potency/bioactivity, and reconstitution time.

With respect to the use of statistical methodology to evaluate lyophilization performance, we do not agree that use of a 95% confidence interval for (b) (4)) is appropriate, particularly with respect to residual moisture acceptance criteria.

We do not agree that, in order to qualify lyophilizer (b) (4) for manufacture of rFXIII, manufacturing of a second batch of rFXIII in lyophilizer (b) (4) based on market demand and using the results from extended sampling from this batch, is appropriate. Should you wish to use lyophilizer number (b) (4) you will either have to:

- a. Perform the studies outlined previously using lyophilizer (b) (4) and submit the results of these studies as part of your complete response, or
- b. Perform the studies outlined previously using lyophilizer (b) (4) and submit the results of these studies as a supplement to an approved application, or
- c. Submit a complete plan for validation of lyophilizer (b) (4) as part of your complete response. Your plan should describe in detail the tests and studies to be performed on your commercial-scale manufacturing batch and your plan for assessing the potential effect of implementation of lyophilizer (b) (4) on product quality. This implementation plan should include your control strategy for commercial production; acceptance criteria for the expected results, and any non-routine tests or sampling that may be pertinent to the plan. Potential reporting categories for this change can be discussed after your complete response is received. Please note that we do not believe that this change (b) (4) lyophilizer) is necessarily within the scope of annual reportable changes.

Additional discussion:

FDA has concerns that by solely relying upon data analysis based on statistical methodology for residual moisture could render it difficult to identify problematic areas within a lyophilizer during production. Evaluating individual test results could be helpful to pinpoint specific problem with the lyophilizer or lyophilization cycle.

Novo Nordisk stated that by using the outlined statistical approach, they believe there is assurance of batch uniformity, and stated that it is hard to assure that every test performed in the lyophilizer and lyophilization cycle validation will pass. FDA noted

that this approach, with respect to lyophilization/lyophilizer validation, appears unique and that it would need to discuss this approach internally and respond to Novo Nordisk at a later date.

For comment 18c, FDA does not agree that the qualification of lyophilizer number (b)(4) for manufacture of rFXIII is within the scope of an annual reportable change. FDA considers the qualification of a new lyophilizer, even if it the same model as a currently qualified lyophilizer, to be categorized as a Changes Being Effected in 30 Days.

Applicant Question 19:

For Item 17 in the Complete Response Letter, the Agency has requested the final container release information for drug product manufactured with drug substance from the Supplementary Process Validation study. The requested information will be submitted as part of the process confirmation report from manufacturing of rFXIII drug product employing drug substance from the supplementary process validation on purification in the complete response to the CR Letter.

Does the Agency agree that the presented information is sufficient to address the deficiency?

FDA Response to Question 19:

Yes.

Additional discussion:

This question was not discussed during this meeting.

Final Comments:

- The comments provided for this meeting were made with concurrence from OBRR upper management.
- OCBQ/DMPQ declines to participate in any additional discussions to clarify the inspectional and CMC issues. All proposals/data should be submitted to the BLA for review.

Decisions made and/or agreements reached:

1. Novo Nordisk will submit information agreed upon during this discussion to the BLA in their response to the Complete Response letter.
2. FDA agreed to Novo Nordisk's proposal to submit to the BLA an interim specification for polysorbate 20, and 3 months before the action due date of the review of Novo Nordisk's Complete Response letter. They will submit the final specification and supporting data.

Issues requiring further discussion:

None.

Action items:

None.

Attachments/Handouts:

1. Copy of presentation

END

Concurrence Page

Application Number: CRMTS #8352

Other Reference Number: STN 125398/0

Letter Type: Meeting Summary (MS)

History: Drafted Debbie Cordaro/ March 21, 2012
 Revised Sonday Kelly/ March 21, 2012; April 12, 2012
 Revised Howard Chazin/ April 11, 2012
 Revised Trevor Pendley/ April 12, 2012

Cc: EDR

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Summary Received: _____
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Rev 11/14/11