

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125577/0 Office: OBRR

Product Information: von Willebrand Factor (Recombinant)

Applicant:

Baxter Healthcare Inc.

Telecon Date/Time: 09-Sep-2015 9:30 AM Initiated by FDA? Yes

Telephone Number: (b) (4)

Communication Category(ies):

1. Advice

Author: JIE HE

Telecon Summary:

Discuss equipment cleaning validation for (b) (4) site. Baxter presented revised acceptance criteria for (b) (4) tests for equipment, and agreed to submit formal response in amendment to the BLA.

FDA Participants:

Jie He, Consumer Safety Officer, OCBQ/DMPQ/MRBII

Qiao Bobo, Ph.D., Acting Team Leader, OCBQ/DMPQ/MRBII

Non-FDA Participants:

Baxter attendees:

| | |
|---------------|---|
| (b) (6) | Director, Quality Operations, (b) (4) |
| (b) (6) | Senior Director, Quality, (b) (4) |
| (b) (6) | Validation Supervisor (b) (4)) |
| Alex Mendoza | Senior Director, Global Process Validation |
| Eli Laba | Director, Quality Systems and Global Validation |
| Mike Guyader | Senior Manager, Global Process Validation |
| Max Fernandez | Senior Manager, Global Regulatory Affairs |

Trans-BLA Group: No

Related STNs: None