

(System Info - 155251 CAGUNGUN NANNETTE 02/12/2011 21:32:10 CAGUNGUN)

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125385/0 Office: OBRR

Product:
Factor XIII Concentrate (Human)

Applicant:
CSL Behring GmbH

Telecon Date/Time: 10-Feb-2011 02:15 PM Initiated by FDA? Yes

Telephone Number: ----(b)(6)-----

Communication Category:
1. Advice

Author: NANNETTE CAGUNGUN

Telecon Summary:

------(b)(4)-----

FDA Participants: Nannette Cagungun, Timothy Lee

Non-FDA Participant: David Desris

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

We spoke with Mr. David Desris to inform him that the -----
------(b)(4)----- to represent
CSL Behring's manufacturing experience. The current acceptance criterion of -----
------(b)(4)-----
-----.

Mr. Desris will get back to us tomorrow after he confers with his colleagues in Germany.