

(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.