

(System Info - 120043 TANKSLEY SARAH 02/16/2010 14:42:35 TANKSLEYS)

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125350/0 Office: OBRR

Product:

Immune Globulin Subcutaneous (Human), 20% Liquid

Applicant:

CSL Behring AG

Telecon Date/Time: 05-Feb-2010 11:00 AM Initiated by FDA? Yes

Telephone Number:

Communication Category(s):

1. Information Request

Author: SARAH TANKSLEY

Telecon Summary:

Telecon regarding cleaning specifications and CCIT testing.

FDA Participants: Sarah Tanksley, DMPQ and Deborah Trout, DMPQ

Non-FDA Participants:

Michel Baur, Head of Quality Control, QM

Christoph Wasem, Head of Biological Quality Control, QM

Renzo Pedrussio, Manager, Development of Pharmaceutical Forms, R&D

Beat Wanner, Head of Aseptic Filling, PRO

Jonathan Imhof, Head of Validation, QM

Florian Lüders, Regulatory Affairs Manager, R&D

Dominique Schaller, Regulatory Affairs Manager, R&D

Urs Meyer, Head of Product Licensing, R&D

King of Prussia

Paula Hines, Sr. Manager, Regulatory Affairs

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Regarding the cleaning specifications, CSL agreed to reassess the [REDACTED] value [REDACTED], and to readjust the value if the data demonstrates they can meet a lower specification.

CSL agreed to the following PMC regarding CCIT validation:

CSL Behring AG commits:

