

Record of Telephone Conversation, September 29, 2011 - Ducord

Submission Type: BLA Submission ID: 125407/0 Office: OCTGT

Product:
Hematopoietic Progenitor Cells,Cord (HPC-C)

Applicant:
Duke University School of Medicine

Telecon Date/Time: 29-Sep-2011 10:00 AM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):
1. Information Request

Author: DONNA PRZEPIORKA

Telecon Summary: Requested revised dataset.

FDA Participants: YY Zhu, D Przepiorka

Non-FDA Participants: J Kurtzberg, --(b)(4)(b)(6)--, B Burnette, R Parrish

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:
Requested revised dataset with missing variables. Discussed what data is actually available. List of variables requested was emailed to the applicant.

Page Last Updated: 11/02/2012

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