

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125562/0 Office: OBRR

Product: Anthrax Immune Globulin Intravenous (Human)

Applicant: Cangene Corporation

Telecon Date/Time: 30-Jan-2015 12:15 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies): 1. Information Request

Author: ROBERT FISHER

Telecon Summary: Request for additional information on exposure-response model to inform review of anthrax animal models

FDA Participants:

Robert W. Fisher
Michael Kennedy
Dorothy Scott

Non-FDA Participants:

Emergent
Christine Hall, Director, Clinical
Bojan Drobic, Scientist, Clinical Research
Yi Hua, Biostatistician
Laura Saward, VP, Winnipeg R&D
Tim Babinchak, Sr. Director, Medical Affairs
Shantha Kodihalli, Director, Preclinical
Darren Ross, Sr. Manager, Programs
Jennifer Wagstaff, Project Manager
Allison Kennedy, Manager, RA
Shelley Toth, Specialist, RA

(b) (4)

BARDA
Drew Albright
Mike Merchlinsky

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

FDA requested additional information on the exposure-response model provided by Cangene to support review of STN 125562/0. FDA inquired why the AUC values cited in the (b) (4) report appeared to be orders of magnitude higher than those cited in other PK summary documents in the BLA. Cangene and (b) (4) clarified that the units used for the exposure-response model were expressed in U*h/L, as opposed to the mU*h/mL and mU*day/mL units provided in other documents. FDA inquired whether the model included time of antibiotic administration as a covariate and was informed that it did not.