

From: Joneckis, Christopher
Sent: Monday, October 13, 2014 01:01 PM
To: Mintz, Paul
Cc: Epstein, Jay; Michaud, Ginette; Golding, Basil; Chazin, Howard;
Scott, Dorothy; Fisher, Robert;
Williams, Alan; Valencia, Iliana; Jain, Nisha
Subject: RE: Justification to Waive a Biologics Products Advisory
Committee Meeting for the Review of
BLA STN 125562/0, Emergent Biosolutions Anthrax Immune Globulin
Intravenous (Human).

Karen, Peter and I feel that there is sufficient justification provided
not to hold the Advisory
Committee Meeting for this BLA.

Thanks

Chris

From: Joneckis, Christopher
Sent: Thursday, September 25, 2014 10:25 AM
To: Mintz, Paul
Cc: Epstein, Jay; Michaud, Ginette; Golding, Basil; Chazin, Howard;
Scott, Dorothy; Fisher, Robert;
Williams, Alan; Valencia, Iliana; Jain, Nisha
Subject: RE: Justification to Waive a Biologics Products Advisory
Committee Meeting for the Review of
BLA STN 125562/0, Emergent Biosolutions Anthrax Immune Globulin
Intravenous (Human).
Paul,
Thanks. Will be discussing and let you know of any comments or outcomes.
Chris

From: Mintz, Paul
Sent: Wednesday, September 24, 2014 4:04 PM
To: Joneckis, Christopher
Cc: Epstein, Jay; Michaud, Ginette; Golding, Basil; Chazin, Howard;
Mintz, Paul; Scott, Dorothy; Fisher,
Robert; Williams, Alan; Valencia, Iliana; Jain, Nisha
Subject: Justification to Waive a Biologics Products Advisory Committee
Meeting for the Review of BLA
STN 125562/0, Emergent Biosolutions Anthrax Immune Globulin Intravenous
(Human).
Dear Chris,
Attached please find a memorandum from OBRR to justify waiving a
Biologics Products
Advisory Committee meeting for the review of BLA STN 125562/0, Emergent
Biosolutions
Anthrax Immune Globulin Intravenous (Human).
I have not copied others in the CBER OD and leave that matter to your
discretion.
We appreciate your consideration of OBRR's points.
Best regards,
Paul

<< File: OBRR Memo Regarding BPAC for Anthrax IGIV 092414.docx >>

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