

Teleconference with Vericel June 17, 2016

FDA attendee: Malcom Moos

Vericel attendee: Lorien Armour

FDA spoke with Vericel about the difficulties with the comparability protocol in 3.2.R, which they appreciated. Vericel agreed to remove it from the BLA to be considered with a revised PAS later, if appropriate.

FDA and Vericel also discussed the minor issue with the (b) (4) assay acceptance criteria and action limit for the (b) (4) , for which Vericel agreed to send in additional information.