

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.