Telecon, December 15, 2021, 1:00 PM – 1:45 PM EST

STN 125752: Moderna (Spikevax)

Subject: Endotoxin testing requirements

FDA Participants:
Sudhakar Agnihothram, Ph.D
Marie Anderson, Ph.D
Alena Dabrazhynetskaya, Ph.D
Maryna Eichelberger, Ph.D
Sara Gagneten, Ph.D
Simleen Kaur, M.S.
Joseph Kulinski, Ph.D
Yen Phan, Ph.D
Josephine Resnick, Ph.D

Moderna Participants:
(b) (6)
Paul Dawidczyk
(b) (6)
Emma Harrington
(b) (6)
Huijuan Li
Linda McKerral
Michelle Olsen
Jennifer White

Discussion:
Moderna discussed the issues regarding the interference of lipids in the endotoxin testing and explained the rationale for performing the endotoxin test (b) (4)
(b) (4)

FDA acknowledged Moderna's explanation. Moderna also questioned whether FDA requires the endotoxin testing on the final drug product (DP) (b) (4)
of LNPs) to be implemented as a release test.

FDA responded that although not required prior to the regulatory action on the SPIKEVAX BLA, FDA would like to request that the endotoxin testing on the complete DP be submitted as a PAS. Moderna agreed.

In the interim, Moderna offered to submit the data of endotoxin testing on the complete DP from their other mRNA vaccines. The response would come in by the end of the

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week – FDA will let Moderna know whether to submit the data to IND 19745 or STN 125752.

Telecon concluded.

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