

Telecon, September 23, 2021, 11:13 AM EST**FDA Participants:**

Sudhakar Agnihothram, PhD Review Committee Chair

Moderna Participants:

Carla Vinals, PhD

Discussion:

In response to the ITEM # 1 in the IR# 1 sent September 14, 2021, requesting Moderna to fill in the dates for their deferred pediatric studies, Moderna requested a waiver for the clinical study to be conducted in individuals 0 to < 6 months of age. This waiver request was submitted in amendment 5 to STN 125752, received on September 23, 2021. The purpose of the call was to clarify to Moderna that waiver request would necessitate the submission of a revised PSP. Moderna agreed to withdraw the waiver request and submit the estimated dates for protocol submission for the study to be conducted in individuals 0 to < 6 months of age as an amendment to STN 125752.