U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #19

Date: November 10, 2021

To: **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
Email: Michelle.Olsen@modernatx.com

From: **Josephine Resnick, Ph.D.**
DVRPA/OVRR/CBER
Email: Josephine.Resnick@fda.hhs.gov

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Postmarketing Reports of Herpes Zoster

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. We have the following requests for additional information:

The FDA is reviewing reports of herpes zoster post receipt of the Moderna Covid-19 Vaccine given the imbalance seen in review of Clinical Trial data in support of the Spikevax BLA (STN 125752/2).

Please provide an update to your previous analysis of postmarketing reports received by Moderna on cases of Herpes Zoster post receipt of Moderna Covid-19 Vaccine. In this report, please include to following:

- Case counts (serious, non-serious) by U.S. and global origin,
- Time to onset (median and range) post-vaccination by dose, demographics (sex and age [median and range])
- An updated observed to expected analysis, overall and stratified by age (<18 year, 18-64 years, >= 65 Years).

Please provide your assessment of this potential safety signal and the occurrence of herpes zoster following receipt of Moderna Covid-19 vaccine.

Please confirm your receipt of this request, and provide your responses as an amendment to STN 125752 at your earliest convenience but no later than November 16, 2021.

Please contact me if you have questions and include Sudhakar Agnihothram (sudhakar.agnihothram@fda.hhs.gov) and Joseph Kulinski (joseph.kulinski@fda.hhs.gov) on all communications.