

## CONCURRENCE PAGE

This page must be uploaded through CBER Connect. Do NOT send this page to the applicant. Do NOT post this page to the Biological Approvals website.

---

**Application #:** STN: BL 125752/0

**Communication Name:** Proprietary Name Acceptable

**Communication ID:** LTR-BLAPNR-01

**Instructions for entering communication into the appropriate regulatory system:**

Letter Type: Proprietary Name Review – Letter (PNA)

Summary Text: Proprietary Name Acceptable

**Drafted by:** Jo Resnick, 9/30/21

**Review History:**

Sudhakar Agnihothram: 09/30/21

Joseph Kulinski: 09/30/2021

Timothy Fritz: 10/05/2021

Rakesh Pandey: 10/04/2021

Oluchi Elekwachi: 10/9/2021

Lisa Stockbridge: 10/5/2021

Review Committee/TL/BC/DD/OD

LTS Chair: Asia Blackwell:

**Concurrence:**

Chair OVR      Sudhakar Agnihothram: 9/30/21

RPM OVR      Josephine Resnick: 10/9/21

BC OVR      Rakesh Pandey: 10/4/21

CSO OVR      David Dickerson: 10/14/2021

**cc:**      CBER Electronic Repository

**END OF CONCURRENCE PAGE**

**The letter begins on the next page.**



Our STN: BL 125752/0

**PROPRIETARY NAME ACCEPTABLE**

ModernaTX, Inc.  
Attention: Michelle Olsen  
200 Technology Square  
Cambridge, MA 02139

October 15, 2021

Dear Ms. Olsen:

Please refer to your Biologics License Application (BLA) submitted and received August 24, 2021, under section 351(a) of the Public Health Service Act for Covid-19 mRNA vaccine, requesting a proprietary name review for SPIKEVAX.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, SPIKEVAX is acceptable.

If you have any questions, please contact the Regulatory Project Managers, Josephine Resnick, Ph.D., ([Josephine.Resnick@fda.hhs.gov](mailto:Josephine.Resnick@fda.hhs.gov)) and Joseph Kulinski, Ph.D., ([Joseph.Kulinski@fda.hhs.gov](mailto:Joseph.Kulinski@fda.hhs.gov)) either by email or telephone at (301) 796-2640.

Sincerely,

Loris D. McVittie, Ph.D.  
Deputy Director  
Division of Vaccines and  
Related Products Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research