



**U.S. FOOD & DRUG**  
ADMINISTRATION

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## Memorandum

Date: September 27, 2021

From: Oluchi Elekwachi, PharmD, MPH, Regulatory Review Officer  
OCBQ/DCM/APLB

Through: Lisa Stockbridge, PhD, Branch Chief  
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Rachel Zhang, Medical Officer, CBER/OVRP\DVRPA\CRB1

Subject: Review of Proposed Proprietary Name **SPIKEVAX** (COVID-19 Vaccine, mRNA) Vaccine  
STN: BLA 125752  
Applicant: ModernaTX, Inc.

Recommendation: **SPIKEVAX – Acceptable**

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## Executive Summary

APLB has completed the proprietary name review (PNR) for the proposed proprietary name, **SPIKEVAX**, for COVID-19 Vaccine, mRNA vaccine. We recommend that the proposed proprietary name, **SPIKEVAX**, be found **Acceptable**.

According to SOPP 8001.4 Review of CBER Regulated Product Proprietary Names, the product office, Office of Vaccine Research and Review (OVRP), makes the final decision on the acceptability of a proposed proprietary name. To meet the PDUFA performance goal, OVRP must communicate this decision to the applicant within 90 days of the receipt of the proprietary name review (PNR) submission. The PDUFA goal date for this PNR is October 19, 2021.

If OVRP accepts our recommendation that the proposed primary proprietary name, **SPIKEVAX**, be found **Acceptable**, we offer the following communication-ready language:

*In consultation with CBER's Advertising and Promotional Labeling Branch, we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations your proposed proprietary name, **SPIKEVAX**, is Acceptable.*

OVR is responsible for communicating CBER's decision to the applicant and should enter the communication issuance date into the FDA electronic record before October 19, 2021, in order to meet the deadline and stop the performance clock. Please notify APLB when this action has been completed.

## **Background**

On August 25, 2021, ModernaTX, Inc. submitted a PNR request for its COVID-19 vaccine (BLA 125752). The proposed proprietary name is **SPIKEVAX** (pronounced *SPĪK-văx*). The proposed indication is for the active immunization for the prevention of disease caused by SARS-CoV-2 (COVID-19) in persons 18 years of age and older.

According to the sponsor, **SPIKEVAX** is coined from the spike protein of the SARS-CoV-2 virus and vaccine. The sponsor proposes the alternative name, (b) (4)

**SPIKEVAX** will be available as a solution for intramuscular injection. It will be administered as a series of two 2 doses: a single 0.5 mL dose, followed by a second 0.5 mL dose 28 days later.

**SPIKEVAX** will be supplied in vials containing sufficient volume to provide 10 individual doses (100 mcg per each 0.5 mL dose). Product will require storage between -25° to -15°C (-13° to 5°F) until ready for use. However, it can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 7 days if not entered (needle-punctured).

The vaccine will be administered by a qualified healthcare professional.

## **Method**

APLB utilized the FDA Phonetic and Orthographic Computer Analysis (POCA) and the following databases:

1. CBER list of Licensed Products ending September 20, 2021, at <http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM149970.pdf>
2. DailyMed at <http://dailymed.nlm.nih.gov/dailymed/about.cfm>
3. Drugs@FDA current through September 20, 2021, at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda>
4. Electronic Orange Book current through September 20, 2021, at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>
5. Google Internet search at <http://www.google.com>
6. Micromedex at <http://www.micromedexsolutions.com/micromedex2/librarian>
7. United States Patent and Trademark Office (USPTO) at <http://www.uspto.gov/trademarks/index.jsp>
8. USAN Stem at <http://www.ama-assn.org/ama1/pub/upload/mm/365/stem-list-cumulative.pdf>

APLB also consulted the review team on the proprietary name.

## **Results**

### **1. Prescreening for Objectionable Naming Practices**

The proposed proprietary name, **SPIKEVAX**, was screened against the following:

- Obvious similarities in spelling and pronunciation
- Manufacturing characteristics
- Medical and/or coined abbreviations
- Inert or inactive ingredients
- Combination of active ingredients
- United States Adopted Name (USAN) stems
- Same proprietary name for products containing different active ingredients
- Reuse of proprietary names
- Dosage form or route of administration
- Dosing interval
- Established or proper name
- Modifiers as components of a proprietary name
  - Use of numerals as modifiers
  - Device-related modifiers
  - Descriptive modifiers
- Brand name extensions (Umbrella branding)
- Dual proprietary names
- Foreign drug proprietary name
- Prescription-to-OTC switch
- Use of symbols
- Incorporation of the applicant's name

### **2. Evaluating for Promotional and Safety Concerns**

#### **a. Promotional Review [21 CFR 201.10 (c)(3), 202.1 (e)(5)(i), and (e)(6)(i)]**

The proposed proprietary name, **SPIKEVAX**, is not regarded to be false, misleading, or fanciful.

#### **b. Look-alike Sound-alike Safety Review [21 CFR 201.10 (c)(5)]**

Since drug products are prescribed through written, verbal, and/or electronic orders, such forms of communication may lead to medication errors, particularly if proprietary or established names sound or look alike. APLB conducted a search using POCA, with DPRF, Drugs@FDA, Cerner US Legend and OTC, CBER Biologic, Orange Book, and RxNorm as data sources, to identify existing names of concern with potential combined orthographic and phonetic similarity to **SPIKEVAX**. There were 105 names found to be moderately phonetically or orthographically similar to **SPIKEVAX**. Differences in dose, form, or strength can mitigate confusion with moderately similar names, and none of the names shared dose, form, or strength with **SPIKEVAX**.

**Recommendation**

APLB recommends that **SPIKEVAX** be found Acceptable at this time.

If you have any questions regarding this review please contact Oluchi Elekwachi, PharmD, MPH Regulatory Review Officer, at 240-402-8930.

BLA 125742

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STN: BLA 125752

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LStockbridge  
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Concurrence box:

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