U.S. FOOD & DRUG ADMINISTRATION

Memorandum

DATE: January 3, 2021

TO: Sudhakar Agnihothram, PhD, Chair, CBER/OVRR/DVRPA
Josephine Resnick, PhD, RPM, CBER/OVRR/DVRPA
Joseph Kulinski, PhD, RPM, CBER/OVRR/DVRPA
Rachel Zhang, MD, Medical Officer, CBER/OVRR/DVRPA

FROM: Oluchi Elekwachi, PharmD, MPH, Regulatory Reviewer
OCBQ/DCM/APLB

THROUGH: Lisa Stockbridge, PhD, Branch Chief
OCBQ/DCM/APLB

SUBJECT: SPIKEVAX (COVID-19 vaccine, mRNA)
Suspension for intramuscular injection
BLA 125752

Sponsor: Moderna Inc.

The sponsor submitted:

☒	Original Application
☐	Major Amendment
☐	Prior Approval Supplement (PAS)
☐	Changes Being Effected (CBE) Supplement

Submission contains:

☐	Prescribing Information (PI)
☒	Patient Package Insert (PPI) – version December 16, 2021
☐	Package and Container - labels

BACKGROUND

On May 28, 2021, Moderna initiated their rolling Biologics License Application (BLA 125752) for their COVID-19 vaccine. Included in their submission was package insert (PI), package and container, and patient package insert (PPI) labeling. The proposed indication for SPIKEVAX BLA (STN 125752) is for the active immunization against coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The action due date (ADD) is January 31, 2022.

Of note, the PPI is FDA-approved labeling that is submitted on a voluntary basis for use in Direct-to-Consumer advertising as an alternative to printing the entire package insert following an advertisement. The PPI format also is used for Medication Guides, when required in Risk Evaluation and Mitigation Strategy (REMS), to assist in explaining the risks and benefits of a prescription product directly to patients.

On December 16, 2021, FDA requested revisions to the PPI. APLB has participated in reviewing the PPI and all revisions submitted to date. At this time, we offer the following comments from a promotional and comprehension perspective.

GENERAL

- Use active voice and command language whenever possible.

- Do not bullet when there only is one concept. Use bulleting to emphasize the importance of a concept.

PATIENT PACKAGE INSERT

- Under "**What should I tell my healthcare provider?"**, Consider amending the bullet:

  had a severe allergic reaction after receiving a previous dose of this vaccine

  to

  had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine

- Under **How is SPIKEVAX given?** Include two sentences stating: "Your doctor will let you know if you need a third dose. Be sure to obtain and maintain access to your vaccination card."

- Under **What are the risks of SPIKEVAX?**, consider bulleting all side effects. Specifically, revise:

Side effects that have been reported in clinical trials with SPIKEVAX include:

- *Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness*
- *General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever*

to

Side effects that have been reported in clinical trials with SPIKEVAX include:

- *Injection site reactions:*
  - *pain,*
  - *tenderness and swelling of the lymph nodes in the same arm of the injection,*
  - *swelling (hardness), and*
  - *redness*
- *General side effects:*
  - *fatigue,*
  - *headache,*
  - *muscle pain,*
  - *joint pain, chills,*
  - *nausea and vomiting, and*
  - *fever*

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

Firm: Moderna Inc.
STN: 125752

Document type: Review Memorandum

Bcc: OElekwachi
APLB Chronologic File
APLB Historical File

History:

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