Our STN: BL 125752/231

ASSIGN / APPROVE
September 6, 2024

ModernaTX, Inc.
Attention: Biliana Nestorova
200 Technology Square
Cambridge, MA 02139

Dear Ms. Nestorova:

Submission Tracking Number (STN) BL 125752/231 has been assigned to your recent supplement to your Biologics License Application (BLA) for COVID-19 Vaccine, mRNA (SPIKEVAX), received August 22, 2024. Your submission is in the form of a Supplement – Changes Being Effected as described under 21 CFR 601.12(c)(5).

We have approved your request to supplement your Biologics License Application for COVID-19 Vaccine, mRNA (SPIKEVAX) to update the package insert to remove references to the single dose vial and to make minor editorial changes and corrections.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 1, dated August 29, 2024.

Please provide your final content of labeling in Structured Product Labeling (SPL) format. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system, (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertisement and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.
We will include information contained in the above-referenced supplement in your biologics license application file.

If you have any questions, please contact the Regulatory Project Manager, Joseph Kulinski, by email at joseph.kulinski@fda.hhs.gov.

Sincerely,

Rebecca Reindel, M.D.
Director
Division of Clinical & Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research