



Our STN: BL 125796/18

## SUPPLEMENT APPROVAL

ModernaTX, Inc.  
Attention: Laila El Asmar, Ph.D.  
325 Binney Street  
Cambridge, MA 02142

December 23, 2024

Dear Dr. El Asmar:

We have approved your request received on July 8, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Respiratory Syncytial Virus Vaccine (MRESVIA), manufactured at the (b) (4)

(b) (4)

(b) (4) to include a carton containing 2 PFS in blister pack, in addition to the approved carton containing 1 PFS blister pack and carton containing 10 PFS blister pack, and revisions to the package insert to update the thaw duration times for the carton containing 1 PFS blister pack, the carton containing 2 PFS in blister pack and the carton containing 10 PFS blister pack.

### LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 2, dated December 17, 2024, and the draft carton and container labels submitted under amendment 2, dated December 17, 2024.

### CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the Package Insert submitted on December 17, 2024. 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>.

The SPL will be accessible via publicly available labeling repositories.

### CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on December 17, 2024, according to the

guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications>.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125796, at the time of use and include implementation information on Form FDA 356h.

## **ADVERTISING AND PROMOTIONAL LABELING**

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 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 advertising 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Jerry P. Weir, Ph.D.  
Director  
Division of Viral Products  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research