U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125769/26

ASSIGN / APPROVE
August 21, 2023

Pfizer Inc.
Attention: Rebecca Klein, PhD
500 Arcola Road
Collegeville, PA 19426

Dear Dr. Klein:

Submission Tracking Number (STN) BL 125769/26 has been assigned to your recent supplement to your Biologics License Application (BLA) for Respiratory Syncytial Virus Vaccine received August 14, 2023. Your submission is in the form of a "Prior Approval Supplement" as described under 21 CFR 601.12(b).

We approved your request to supplement your Biologics License Application for Respiratory Syncytial Virus Vaccine (ABRYSVO) manufactured in your establishments operating under U.S License Number 2001, to include a revised Lot Release Protocol and Package Insert consistent with those reviewed and approved under STN (BL) 125768/0 for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. 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 these changes.

We will include the information contained in the above-referenced supplement in your biologics license application file.

If you have any questions, please contact the Regulatory Project Manager, Laura Montague, by email (Laura.Montague@fda.hhs.gov).

Sincerely,

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