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Pfizer Research and Development

28 April 2025

David Kaslow, M.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

Re: BLA 125769/481 ABRYSVO™ Vaccine (RSVpreF; PF-06928316)

RESPONSE TO PREA NON-COMPLIANCE LETTER (STN 466)

Dear Dr. Kaslow,

The purpose of this submission is to provide Pfizer's RESPONSE TO PREA NON-COMPLIANCE LETTER, dated 24 March 2025 (BL 125769/466).

On 10 February 2025, Pfizer submitted a Deferral Extension Request for PREA PMR#4. On 26 March 2025, following receipt of the aforementioned PREA NON-COMPLIANCE LETTER, the FDA granted the deferral extension (BLA STN 125769/439). The new Final Report Submission milestone date for PMR#4 is 30 June 2025.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at (b) (6) or via e-mail at Helen.B.Hartman@pfizer.com.

Sincerely,

Helen B. Hartman, Ph.D.
Director
Global Regulatory Sciences, Vaccines

Pfizer Inc.

cc: Goutam Sen, Ph.D.