DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
(b) (6)

**Chair Review Memorandum**

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| **Date**: | September 26, 2025 |
| **BLA/STN#:** | 125742/656 |
| **From**: | (b) (6) |
| | (b) (6) |
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| **Through**: | (b) (6) |
| | (b) (6) |
| **Applicant**: | BioNTech Manufacturing GmbH/Pfizer Inc. |
| **Product:** | COVID-19 Vaccine, mRNA (COMIRNATY) |
| **Supplement Type:** | Efficacy Supplement |
| **Submission Date:** | March 18, 2025 |
| **Action Due Date:** | January 16, 2026 |

## 1. Background

The Biologics License Application (BLA) for COVID-19 Vaccine, mRNA (COMIRNATY) was originally approved on August 23, 2021 (STN 125742/0) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. An Efficacy Supplement to the Biologics License Application (sBLA) was approved on July 8, 2022 (STN 125742/45) to include use in adolescents 12 through 15 years of age. The current efficacy sBLA submission includes data to support use in children 5 through 11

years of age and data to update the monovalent Omicron sublineage JN.1-based COMIRANTY (2024-2025 Formula) to a monovalent Omicron sublineage LP.8.1-based COMIRNATY (2025-2026 Formula) for use in the United States beginning Fall of 2025.

## 2. Submission Summary

The current application, STN 125742/656, was initially submitted on March 18, 2025, to include a 10-mcg single-dose vial (SDV) for use in children 5 years through 11 years of age. This supplement was amended on July 18, 2025, to also include all information previously submitted to: (1) STN 125742/696 – to include the 2025-2026 Formula and associated labeling revisions for use in individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19; and, (2) STN 125742/634 – to include concomitant administration of COMIRNATY with RSV vaccine with and without influenza vaccine in individuals 65 years of age and older. On August 20, 2025, the Applicant withdrew all submitted information pertaining to STN 125742/634 (see Regulatory Considerations below for additional details).

Submission of this supplement fulfills the following Pediatric Research Equity Act (PREA) PMRs:

- PMR #1 (STN 125742/686): Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in children 5 years through 11 years of age.

- PMR #3 (STN 125742/686): Deferred pediatric Study C4591048 Substudy E to evaluate the safety and effectiveness of a single dose of COMIRNATY in children 5 years through 11 years of age.

## 3. Summary of Regulatory Activity

**Information Requests**

There were 57 information requests associated with this supplement (including 5 information requests associated with STN 125742/696 prior to this supplement being combined into STN 125742/656) that were issued to the Applicant. All requests were responded to in a timely manner and routed to the requestor(s) for review. Details regarding information requests, along with corresponding amendments and review verification can be found in the Documentation Review Memorandum.

**Environmental Assessment**

The sBLA included a request for categorical exclusion from an Environmental Assessment under 21 CFR 25.31. FDA concluded that this request is justified, and no extraordinary circumstances exist that would require an environmental assessment.

**Unique Ingredient Identifier (UNII) Codes**

UNII code assignment was requested for STN 125742/656 on June 17, 2025. A new UNII code for the Active Ingredient/Active Moiety/Basis of Strength BNT162b2 Omicron (LP.8.1) was assigned and the Inactive Ingredients were also provided and were unchanged. The UNII code assignments were shared with the CMC reviewer. A UNII Code Assignment Letter was sent to the Applicant on August 5, 2025.

**Lot Clearance**

A lot clearance check for STN 125742/656 was returned on August 1, 2025 indicating the lot(s) associated with this BLA/supplement will be released upon completion of protocol review, any requested sample testing and approval of the BLA/supplement.

**Compliance Check**

A Compliance Check was returned on August 26, 2025, indicating that there are no ongoing or pending investigations or compliance actions with respect to the impacted facilities or its product(s). Therefore, the (b) (6) (b) (6) did not object to the approval of this supplement.

## 4. Reviews Summaries

**Chemistry, Manufacturing and Controls (CMC)/Facilities**

COMIRNATY (also known as BNT162b2) is a sterile suspension for intramuscular injection, supplied as SDVs or as a liquid suspension in single-dose glass prefilled syringes (PFS). Each 0.3 mL dose of COMIRNATY (2024-2025 Formula) was formulated to 30-mcg of a nucleoside-modified messenger RNA (modRNA,) encoding the viral spike (S) glycoprotein of SARS-CoV-2 and four lipids: ALC-0315; ALC-0159; DSPC; and cholesterol.

This submission provides CMC information in support of a single dose of COMIRNATY (2025-2026 Formula), encoding the viral S glycoprotein of SARS-CoV-2 Omicron variant sublineage LP.8.1 containing 10-mcg of modRNA in a SDV for use in children 5 years through 11 years of age. The 10-mcg dose is formulated at an RNA concentration of 0.033 mg/mL in Tris/sucrose buffer, filled at a (b) (4) fill volume per SDV, and administered without dilution in a 0.3 mL injection volume.

In addition, this submission includes CMC information supporting the production of the 30-mcg dose of COMIRNATY (2025-2026 Formula) encoding the viral S glycoprotein of SARS-CoV-2 Omicron variant sublineage LP.8.1 for use in individuals 12 years of age and older.

The commercial expiry dating period proposed for the 0.033 mg/mL DP for the 10-mcg SDV presentation is 18 months when stored at the long-term storage condition of -90°C to -60°C. This expiry dating period is based on (b) (4) months of stability data on the (b) (4) primary stability/clinical batches (Original monovalent; 10-mcg dose, 0.033 mg/mL, filled at (b) (4) and 18 months of stability data from the (b) (4) 0.033 mg/mL DP PPQ lots manufactured at Puurs (Bivalent [Original and Omicron BA.4/BA.5]; 10-mcg dose, 0.033 mg/mL, filled at (b) (4) or (b) (4) Both primary and PPQ stability studies are

complete. Stability data at both long-term and accelerated storage conditions indicate a similar stability profile and are supportive of the proposed expiry dating period of (b) (4) months for the 10-mcg SDV presentation. The expiry dating period for the 30-mcg 2025-2026 Formula (Omicron (LP.8.1) Variant DP formulated at 0.1 mg/mL for PFS, refrigerated) is (b) (4) months (See Product Reviewer's Memorandum for more detailed discussion).

*Clinical Assays*
SOPs and validation reports of SARS-CoV-2 assays used in clinical studies were previously provided and reviewed as outlined in the Product Reviewer's Memorandum and determined to be suitable for their intended purpose.

*Facilities*
As noted above, the initial supplement (STN 125742/656) was submitted to include a 10-mcg single dose for use in children 5 years through 11 years of age. The 10-mcg presentation was originally authorized in EUA 27034.324, and the use of the 0.033 mg/mL formulation (used to produce the 10-mcg presentation) was authorized in EUA 27034.741. There are no changes to the (b) (4) or drug substance (DS) manufacturing between the 10-mcg presentation and the 30-mcg presentation previously approved for individuals 12 years of age and older. While the submission does not include a 3.2.S Module, except in regards with the formula update, information was provided about DS facilities in amendments STN 125742/656.7 (dated June 10, 2025) and STN 125742/656.8 (dated June 13, 2025).

The 10-mcg filling volume and container closure system is identical to the approved 30-mcg presentation. There are no changes to the microbial in-process and release specifications. All manufacturing equipment, facilities and processes were previously approved or authorized for vaccine formulations under STN 125742/0 (See Facilities and Product review memoranda for more detailed discussions).

The 10-mcg presentation is filled into SDVs at Pfizer Manufacturing Belgium NV (referred to as Pfizer Puurs) and the 30-mcg presentation is filled into glass PFSs at Pfizer Puurs. There are no proposed changes for the 30-mcg presentation container closure system.

**Clinical and Statistics**
The reviews encompassed three clinical studies:

- Study C4591007 evaluated a 2-dose series of BNT162b2 (Original monovalent) in COVID-19 vaccine-naïve children 5 years through 11 years of age (Two-part design: open-label dose finding Phase 1 and blinded, saline placebo-controlled Phase 2/3) and a single dose of BNT162b2 (Original monovalent) following the 2-dose series (open-label extension study).

- Study C4591048 Substudy D was an open-label study that evaluated a single dose of BNT162b2, Bivalent (Original and BA.4/BA.5), in COVID-19 vaccine-experienced children 5 years through 11 years of age.

- Study C4591048 Substudy E was an open-label study that evaluated a single dose of BNT162b2 (Monovalent XBB.1.5) in COVID-19 vaccine-naïve children 5 years through 11 years of age.

The statistical review team did not identify any major statistical issues that would preclude approval of this sBLA. All success criteria for the immunogenicity objectives of Studies C4591007, C4591048 Substudy D and Study C4591048 Substudy E were met, and the clinical review team found no notable patterns in safety results. Detailed analyses of the study data supporting the indication requested by the Applicant on March 18, 2025, are provided in the clinical and statistical review memoranda.

The clinical and statistical teams recommend approval of STN 125742/656 with the indication initially submitted on March 18, 2025.

**Bioresearch Monitoring (BIMO)**

BIMO inspections were issued for domestic clinical investigator (CI) sites participating in the conduct of study C4591048 and C5481001. The inspections did not reveal significant problems impacting the data submitted in support of this supplement. A detailed inspection account is documented in the BIMO Review Memoranda.

**Pharmacovigilance**

The pharmacovigilance review team assessed the Applicant's pharmacovigilance plan (PVP), version 5.0 (dated June 11, 2025), which updated the use of COMIRNATY with the 2025-2026 Formula for active immunization to prevent COVID-19 disease in individuals 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19, and all individuals 65 years of age and older. The purpose of the PVP review is to determine whether any safety-related studies such as Postmarketing Requirements (PMRs) and/or Postmarketing Commitments (PMCs) are warranted, or if Risk Evaluation and Mitigation Strategies (REMS) are required for COMIRNATY.

The review encompassed the Clinical Overview, Clinical Safety Summary, and Clinical Study reports for Study C4591007, Study C4591048 Substudy D, and Study C4591048 Substudy E. The review also included the Applicant's updated global approval and distribution data for COMIRNATY and Pfizer-BioNTech COVID-19 vaccines (STN 125742/656.26) submitted to this supplement on August 8, 2025, per CBER's request. Additionally, the Vaccine Adverse Event Reporting System (VAERS) was queried on August 12, 2025, for U.S. reports following vaccination with monovalent Pfizer-BioNTech COVID-19 Vaccine for individuals 5 years through 11 years of age and for individuals 12 years of age and older. The queries used vaccination dates starting from August 23, 2024.

The pharmacovigilance review team concluded that given the overall safety profile for all formulations of the Pfizer-BioNTech COVID-19 vaccine established during its extensive use, and the same manufacturing process used for manufacturing of COMIRNATY (2025-2026 Formula), the current PVP (version 5.0) is acceptable and adequate to monitor postmarketing safety with routine pharmacovigilance in accordance with 21 CFR 600.80. The available safety data do not substantiate a need for a Risk Evaluation and Mitigation Strategy (REMS). A detailed review can be found in the pharmacovigilance review memorandum.

**Labeling**

The product labeling submitted to STN 125742/656.0 (dated March 18, 2025), included carton and container labels for COMIRNATY (2025-2026 Formula) 10-mcg SDV and draft Package Insert (PI) with Patient Package Insert (PPI) for individuals 5 years of age and older. This supplement was amended on July 18, 2025, to also include all information previously submitted to STN 125742/696 - to include the 2025-2026 Formula and associated labeling revisions for use in individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. The (b) (6) found the Package Insert (PI), Patient Package Insert (PPI) and carton/container labels to be acceptable from a promotional and comprehension perspective. The Review Committee negotiated revisions to the draft labeling with the Applicant as described in the Labeling Review Memorandum. Final draft labeling was submitted in amendments STN 125742/656.16 (dated July 11, 2025), STN 125742/656.18 (dated July 16, 2025), STN 125742/656.30 (dated August 8, 2025), and STN 125742/656.43 (dated August 26, 2025). (See Section 5. Regulatory Considerations - *Labeling Implications*, and refer to the Regulatory and (b) (6) Review Memos for additional details on the labeling review.)

**Clinical Data Validation**

SDTM and ADaM standardized datasets from the following clinical studies underwent validation by the CBER (b) (6) C4591001, C4591007, C4591048 (substudies D and E), and C4591054. The review team's assessment of the validation results revealed no significant issues that would impact review of the datasets.

**Digital Health Technology**

The Applicant used an electronic diary safety event reporting system (e-diary) to collect solicited local and systemic adverse reactions for 7 days following each vaccination in the conduct of the studies submitted to this sBLA. The (b) (6) consult reviewer reviewed the clinical study reports and protocols for C4591007, C4591048 (substudies D and E), and C4591054, along with corresponding SDTM and ADaM datasets, and responses to their information request. The (b) (6) reviewer verified the provided e-diary transmission rates which are acceptable during period of active and likely reactogenicity. The e-diary transmission was also comparable across the treatment arms. Overall, there are no significant issues or concerns regarding the e-diary safety data transmission.

## 5. Regulatory Considerations

**Consolidation of efficacy supplements submitted to STN 125742/656**

As noted above, the review of STN 125742/656 was initially conducted in parallel with review of two additional sBLAs for COMIRNATY as follows:

- STN 125742/696 for use of COMIRNATY (2025-2026 Formula) in the United States beginning in the fall of 2025 individuals who are 65 years of age and older, or 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19, submitted on June 2, 2025.
- STN 125742/634 to include concomitant administration of COMIRNATY with RSV vaccine with and without influenza vaccine in individuals 65 years of age and older, submitted on November 26, 2024. The sBLA included the results of Study C5481001 to support concomitant administration of BNT162b2, Bivalent (Original and Omicron BA.4/BA.5) and ABRYSVO (Respiratory Syncytial Virus (RSV) Vaccine), with and without Fluzone High-Dose Quadrivalent seasonal influenza vaccine in healthy participants 65 years of age and older.

On July 11, 2025, and July 15, 2025, OVRR management and the Applicant discussed by teleconference a proposal to consolidate the three sBLAs for the purposes of providing a more efficient review and coordination of regulatory action.

The Applicant agreed to this approach and submitted amendments STN 125742/656.21 and STN 125742/656.22 on July 18, 2025, containing all the information that had been previously submitted to STN 125742/696 and STN 125742/634, respectively. The Applicant then submitted requests for withdrawal to STN 125742/696 and STN 125742/634 on July 22, 2025. Withdrawal Acknowledgement letters for STN 125742/696 and STN 125742/634 were issued on August 4, 2025.

*Withdrawal of amendment STN 125742/656.22*

On August 20, 2025, the Applicant submitted amendment STN 125742/656.35 (dated August 20, 2025) withdrawing amendment STN 125742/656.22 (dated July 18, 2025), which included information regarding the concomitant administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent and ABRYSVO, with and without Fluzone High-Dose Quadrivalent seasonal influenza vaccine in healthy participants 65 years of age and older. The Applicant also submitted amendment STN 125742/656.40 (dated August 25, 2025) withdrawing amendment STN 125742/656.29 (dated August 7, 2025), which had also included information pertaining to concomitant administration not included in amendment STN 125742/656.22 (dated July 18, 2025). In their withdrawal request, the Applicant referenced the (b) (4)

Prior to withdrawal, review of the information pertaining to the concomitant administration was completed by CMC, clinical, statistical, pharmacovigilance, dataset integrity, digital health technology and BIMO disciplines. Detailed reviews (b) (5)

*Labeling Implications*

Amendment STN 125742/656.35 (dated August 20, 2025) included an updated draft PI reflecting the removal of information pertaining to concomitant administration of COMIRNATY with RSV vaccines, with or without high dose seasonal influenza vaccine.

The Applicant had printed the PI containing the concomitant administration information "at risk" (prior to approval of this submission), and subsequently requested that FDA consider enforcement discretion to permit distribution of the 13 lots of COMIRNATY vaccine already packaged with the previous version of the PI (submitted in amendment STN 125742/656.20; dated July 17, 2025) accompanied by a Dear Health Care Provider (DHCP) letter.

Final Draft PI and draft revised DHCP Letter were submitted in amendment STN 125742/656.43, (dated August 26, 2025), as well as a proposal for distribution of the DHCP Letter with the affected lots (MY9547; MY9548; MY9550; NA0587; NA0589; NA0590; NA0738; NA0739; NA0846; NA4451; NA4452; NA4457; NA4459) of COMIRNATY.

The following plan for DHCP letter distribution was outlined in amendment STN 125742/656.43 (dated August 26, 2025):

> The Pfizer Comirnaty vaccine is shipped to vaccination centers via two paths: direct shipments from Pfizer-managed logistics centers and shipments via third-party wholesalers.
>
> For direct shipments from Pfizer-managed logistics centers: Pfizer will include printed copies of the DHCP letter inside every thermal shipper. The letter will be placed immediately below the lid, so it is easily visible when the thermal shipper is opened at the vaccination center.
>
> For shipments via third-party wholesalers: Pfizer will work with each wholesaler to incorporate procedures to place copies of the letter in a visible location with all Comirnaty vaccine shipments.
>
> Out of an abundance of caution, Pfizer will also take additional steps to communicate:
>
> 1. Pfizer will also work with all Retailers to make sure their Vaccinators have access to this document

2. Pfizer will leverage multiple electronic means to send the DHCP letter in advance to all Comirnaty customers, including an electronic platform named "e-Cast" that Pfizer regularly uses for a multitude of communications as well as emails to wholesalers and customers

Pfizer will continue to evaluate additional options for communication of the Dear HCP Letter to ensure speed and reach to customers and vaccinators.

The Applicant was informed on August 26, 2025, that FDA does not intend to object to distribution of certain lots of COMIRNATY® (COVID-19 Vaccine, mRNA) 2025-2026 Formula that contain unapproved Prescribing Information inside the cartons.

**Review Schedule**

At the time of initial submission of STN 125742/656, the Applicant requested Priority Review designation, referencing the provisions outlined in the PDUFA and FDA Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014). The Applicant's rationale for Priority Review designation was reviewed and discussed by the review team with a recommendation that the request not be granted because the criteria for Priority Review designation had not been met (See Clinical Review Memo). This supplement was accepted for filing with Standard Review designation, with a PDUFA goal date of January 16, 2026. Priority Review designation was not requested for STN 125742/696.

**Center Director Decisional Memorandum Summary**

CBER Office of the Center Director's (OCD) Center Director Decisional Memorandum explains CBER OCD's decision on approval of STN 125742/656 for use of COMIRNATY in children 5 years through 11 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. CBER OCD's decision was based on consideration of the reviews and recommendations of the review team, pertinent portions of the Applicant's submission, and research on this topic in the peer-reviewed literature. The memorandum details CBER OCD's dissent from certain aspects of the review team's conclusions.

*Revised Indications and Usage, and Associated Labeling*

This supplement contains data submitted by the Applicant in support of their proposed COMIRNATY indication: "Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older." Following a thorough multidisciplinary review, as noted above in Summary of Regulatory Activity, the review team determined that the data submitted to this supplement are in support of the Applicant's proposed indication.

CBER OCD issued information requests that were sent to the Applicant on May 27, 2025 and June 6, 2025, requesting revised labeling to update the indication to the following:

> "COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
> COMIRNATY is approved for use in individuals:
> • 65 years of age and older, or
> • 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19."

The Applicant submitted amendment STN 125742/656.7 (dated June 10, 2025) containing a revised FDA form 356h and PI to align with the proposed revised labeling submitted in STN 125742/696 and CMC information to support the 10-mcg variant vaccine of COMIRNATY (2025-2026 Formula). Details and justifications for these revisions are included in the CBER Center Director Decisional Memorandum dated August 25, 2025.

*Request to study Spike protein persistence*
On August 21, 2025, CBER OCD notified the Applicant that a signal of risk exists for Post-COVID-19 Vaccination Syndrome (PCVS, potentially linked to persistence of vaccine-derived spike protein in recipients. CBER OCD requested that the Applicant conduct a comprehensive 506B PMC study to assess additional monitoring for spike protein persistence. The Applicant submitted their proposal in amendment STN 125742/656.42 (dated August 26, 2025) (see 6. Postmarketing Agreements). The proposed study design, objectives, and milestone dates were reviewed by CBER OCD and determined to be acceptable.

## 6. Postmarketing Agreements

The Applicant submitted study protocol concept sheets in response to the CBER OCD information requests submitted on May 27, 2025, June 6, 2025, and August 21, 2025. Details of the studies and corresponding milestone dates were reviewed by CBER OCD and determined to be acceptable. Below are the agreed upon Section 506B PMCs and their corresponding milestones:

1. Prospectively designed study to evaluate safety and immunogenicity of COMIRNATY (COVID-19 Vaccine, mRNA) (2025-2026 Formula) in participants 65 years of age and older and in participants 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

   Final Protocol Submission: August 30, 2025
   Study Initiation: September 30, 2025
   Interim Results: February 28, 2026
   Study Completion Date: July 31, 2026
   Final Report Submission: September 30, 2026

2. A randomized, double-blind, placebo-controlled clinical study evaluating the safety and efficacy of a BNT162b2 variant-adapted vaccine in adults 50 years through 64 years of age without high-risk conditions for severe COVID-19.

   Final Protocol Submission: September 30, 2025
   Study Initiation: November 30, 2025
   Interim Results: May 31, 2026
   Study Completion Date: July 31, 2026
   Final Report Submission: January 31, 2027
   Benefit/Risk Assessment Submission: May 31, 2027

3. Prospectively designed study to evaluate safety and immunogenicity of COMIRNATY (COVID-19 Vaccine, mRNA) (2025-2026 Formula) in participants 5 years through 11 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

   Final Protocol Submission: August 30, 2025
   Study Initiation: September 30, 2025
   Interim Results: February 28, 2026
   Study Completion Date: July 31, 2026
   Final Report Submission: September 30, 2026

4. A prospective, exploratory, placebo-controlled, randomized study to evaluate detection of circulating SARS-COV-2 spike antigen and self-reported symptoms of post-COVID-19 vaccination syndrome or Long COVID symptoms at Month 1, 3, 6, and 12 in vaccine and control arms.

   Final Protocol Submission: January 31, 2026
   Study Initiation: April 15, 2026
   Study Completion Date: April 30, 2027
   Final Report Submission: October 31, 2027
   Benefit/Risk Assessment Submission: October 31, 2027

For Scientific and Regulatory Rationale (as per CBER SOPP 8415) for requesting 506 PMC Studies listed above, please refer to the CBER OCD review memorandum dated August 25, 2025.

**7. Recommended Regulatory Action**

Based on a comprehensive review of the clinical data, product-related data, and labeling in this efficacy supplement, the Review Committee recommends approval of STN 125742/656 for the following indication: "COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older." The Review Committee recommends approval of the 2025-2026 Formula and associated labeling revisions.

The Review Committee recommends approval of a new 10-mcg SDV presentation and concurs that the Applicant has fulfilled PMRs #1 and #3 established in PREA PMR Release/Issue New PREA PMR letter STN 125742/686 (dated August 15, 2025). The Review Committee recommends (b) (5)