21 August 2026

Tanya Wroblewski, MD
Division Director
Division of Nonmalignant Hematology
Office of Cardiology, Hematology, Endocrinology,
and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ATTN: Rolanda Bailey, Regulatory Project Manager

RE: BLA 761148
Rolvedon® (eflapegrastim-xnst) injection
RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED
eCTD Sequence No. 0247

Dear Dr. Wroblewski,

Reference is made to Biologic License Application (BLA) 7611248 for Rolvedon® (eflapegrastim-xnst) injection approved on 09 September 2022.

Reference is also made to the Notification of Non-compliance with PREA dated 27 July 2026. Assertio Specialty Pharmaceuticals, LLC (ASP) is submitting in Section 1.17.2 the response to the Agency's notification in accordance with the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 335c(d)(1)].

ASP appreciates the clarification of the 12 August 2024 Preliminary Meeting Comments correspondence from the Agency and further acknowledges that based on the Agency's recent comments, has not met the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application, *i.e.,* specifically, the pediatric assessment (PMR 3891-2) due June 2026.

ASP respectfully requests a deferral extension of both PMR 3891-1 and PMR 3891-2. The proposed timelines as submitted on the 15 August 2024 Type B Meeting Request are provided in Section 1.17.2 of this submission.

Please consider the information in this submission confidential. Kindly obtain written consent from Spectrum prior to disclosure to any person outside of the Food and Drug Administration. If you have any questions concerning this submission, please feel free to contact me by telephone at 224-416-6291, facsimile at 510-744-8001, or email at RA@assertiotx.com.

Sincerely,



Ryan Langner
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Executive Director, Operations
100 S. Saunders Rd. Suite 300
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ELECTRONIC SUBMISSION SPECIFICATIONS

Virus Protection Statement:	This submission is virus free
Anti-Virus Software Information:	CrowdStrike, Version 7.13.18307.0 or later