



March 20, 2026

Director  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Hematology Products  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

**Re: BLA 761126: SN0101: Revised Pediatric Study Plan**

Dear Sir or Madam:

Reference is made to a BLA resubmission on April 24, 2023 for TX01, Methionyl Human Granulocyte Colony-Stimulating Factor (G-CSF, recombinant) submitted by Tanvex under section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)) as a biosimilar product candidate with US-licensed Neupogen® as the reference product.

Reference is also made to a Supplement Request from FDA dated Feb 25, 2026 in which it was indicated that the terms of the post-marketing requirement # 4399-1 were not met because our report submitted in February 2025 that was intended to address that commitment did not include a supplement to the approved BLA with proposed labeling changes.

The purpose of this submission is to respond to that Supplement Request by requesting an amendment to our Pediatric Study Plan (“PSP”) for Nypozi (filgrastim-txid). The justification for this amendment is included with the proposed revision to the PSP.

This submission includes:

- [FDA Form 356h-0010](#)
- Cover letter-0101 with attachment
  - [PSP amendment justification](#)
- Module 1-9 Pediatric Study Plan Revised
  - [Pediatric Study Plan Revised March 2026](#) (clean, pdf)
  - [Revised PSP redlined 26March 2026](#) (word)

Please don't hesitate to let us know if there are any questions.

Sincerely,

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