Tris Pharma, Inc
2031 Route 130
Monmouth Junction,
New Jersey 08852

October 27, 2025

Tiffany R. Farchione, MD
Director, Division of Psychiatry
Office of Neuroscience
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Document Control Room
10903 New Hampshire Avenue, Silver Spring,
Building 22, Suite 4200, MD 20993

Re: NDA 210526, Sequence 0387

DYANAVEL® XR (amphetamine) Extended-Release Tablets, 5 mg, 10 mg, 15 mg and 20 mg

RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Farchione

Reference is made to the approved NDA 210526 for Dyanavel XR (amphetamine) extended-release tablets and to the notification of non-compliance with PREA letter (dated 09/10/2025) and received September 15, 2025, for not having submitted a pediatric assessment for post marketing requirements PMR 4179-2 and PMR 4179-3. This submission includes a formal written response to the PREA non-compliance letter.

Per previous agreement with the FDA, fulfillment of PREA requirements for Dyanavel XR Tablet (NDA#210526) PMR/PMC will be fulfilled once the requirements are fulfilled for the Dyanavel XR Suspension (NDA 208147). No separate revised protocols are submitted to IND 129044 (Amphetamine ER Tablets), and we request the Agency to refer to IND 116985 (Amphetamine ER Oral Suspension) for revised protocols for fulfillment of the above two studies required in Dyanavel XR Tablet (NDA#210526). The studies with Amphetamine ER Oral Suspension are currently delayed.

Please note, we await a formal communication from the FDA which we have been advised is forthcoming regarding the PREA studies in 4 to less than 6 years old, now that the FDA has approved the safety labeling changes pertaining to the risks for pediatric patients with ADHD younger than 6 years of age when taking the same stimulants. We anticipate that our next steps regarding the PREA studies will be clearly defined upon receipt of the anticipated FDA's communications.

This electronic submission has been scanned for viruses (see the Electronic Submission Specifications below) and is being sent via ESG.

Please forward any written communications and any questions or comments regarding this application to TrisRA@trispharma.com or telephone (732) 355-7027.

Sincerely,

Rashmi Aravind

Digitally signed by Rashmi Aravind DN: C=US, E=raravind@trispharma.com, OU=Director of Regulatory Affairs, O="Tris Pharma, Inc.", CN=Rashmi Aravind. Reason: I have reviewed this document. Date: 2025.10.27 17:38:59 -05:00

Rashmi Aravind
Sr. Director, Regulatory Affairs

Electronic Submission Specifications

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Anti-Virus Program	**Bitdefender Endpoint Security Tools**
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Virus Definition Date	October 27, 2025
Submission Size	Approximately 3 MB

The Technical point of contact for this submission is:

Name	**Ivan Moningka**
Phone Number	(732) 823-4970
Email Address	imoningka@trispharma.com