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

April 1, 2026

Tiffany R. Farchione, M.D
Office of Neuroscience
Acting Director, Division of Psychiatry Products
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring,
Building 22, Suite 4200, MD 20993

Reference: **NDA 217645, Sequence 0162**

ONYDA XR (Clonidine Hydrochloride Extended-Release Oral Suspension, 0.1 mg per mL (equivalent to 0.09 mg Clonidine base per mL)

RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Farchione,

Reference is made to the NDA 217645, for Onyda XR (clonidine hydrochloride) extended-release oral suspension, approved on May 24, 2024, IND 128004 and to the deferred pediatric studies required by section 505B(a) of the FDCA, identified as PMR 4636-2 in the approval letter.

In accordance with these postmarketing requirements, Tris Pharma Inc. (Tris), submitted the study protocols under PREA for PMR 4636-1 and 4636-2 to the IND 128004 on January 31, 2024. The protocols were temporarily withdrawn on February 7, 2024, and resubmitted after NDA approval on July 30, 2024 (Seq#0009).

Tris received information requests (IR)s from the Agency on September 27, 2024, and October 25, 2024, and provided a complete response to both the IRs on December 24, 2024. Additional Agency comments were received on February 20, 2025, which were addressed in updated protocols submitted on October 27, 2025. Further comments were received on January 20, 2026, and Tris is currently addressing these comments.

The study cannot be initiated until protocol finalization is complete. Due to multiple rounds of Agency feedback requiring protocol revisions, the finalization of the protocol has been delayed. As a result, the study start and completion timelines have been correspondingly impacted.

Reference is also made to February 18, 2026, notification of non-compliance with PREA received by Tris on February 25, 2026, for not having submitted a pediatric assessment for PMR 4636-1. This submission includes a formal written response to the PREA non-compliance letter.

Tris is finalizing the study protocols to incorporate remaining Agency feedback and plans to submit a comprehensive update shortly. In light of the evolving FDA perspective on pediatric clinical trial conduct, Tris is evaluating [redacted] (b) (4) –based approach to support and potentially fulfill the above mentioned postmarketing study requirements. This approach aims to align with emerging FDA perspectives, prioritize patient wellbeing, and potentially restoring the program to the previously agreed-upon PREA timelines. Revised timelines will be proposed once alignment with the Agency is achieved.

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: 2026.04.01 16:12:42 -05:00

Rashmi Aravind

Senior Director, Regulatory Affairs

Electronic Submission Specifications

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The technical point of contact for this submission is:

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