



Tris Pharma, Inc.
2033 Route 130
Monmouth Junction,
New Jersey 08852

April 23, 2020

Tiffany Farchione, M.D
Acting Director, Division of Psychiatry Products
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

**Reference: NDA 208147, Dyanavel® XR (amphetamine) extended-release oral suspension,
Sequence 0295**
RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Farchione,

Reference is made to the approved NDA 208147 for Dyanavel® XR (amphetamine) extended-release oral suspension and the March 5, 2020 PREA Non-Compliance Letter.

In response to the above-referenced letter, Tris Pharma, Inc. (Tris) acknowledges the delay and advises the Agency that start-up activities for the efficacy study 2970-2 (b) (4) had begun prior to the COVID 19 Pandemic. (b) (4) now been paused temporarily prior to enrolling patients due to the pandemic and due to protocol changes recommended recently by the CRO.

The tentative timelines, considering the anticipated impact of the COVID 19 Pandemic, are:

Efficacy (2970-2)

Study Completion: (b) (4)

Final Report Submission: (b) (4)

(b) (4)

A cross-reference response letter is also being submitted to the Investigational New Drug Application for Amphetamine ER Suspension, IND 116985.

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 the undersigned at csax@trispharma.com and to TrisRA@trispharma.com or telephone (732) 355-7027.

Sincerely,

Carol R. Sax
Digitally signed by Carol R. Sax
Reason: I am the author of this document
Date: 2020.04.23 14:40:05 -0400

Carol R. Sax
Director, Regulatory Affairs

Electronic Submission Specifications

This submission is compliant with FDA's Guidelines for Industry and current eCTD Specifications

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway.

Anti-Virus Program	Trend Micro Security Standard AntiVirus Software
Program Version	20.0.2041
Virus Definition Date	April 23, 2020
Submission Size	Approximately 3 MB

The Technical point of contact for this submission is:

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