24 May 2024

Tiffany Farchione MD
Director, Division of Psychiatry
CDER Central Document Room
FDA/Center for Drug Evaluation and Research (CDER)
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 20705-1266

**RESPONSE TO PREA NON-COMPLIANCE LETTER**

**RE: NDA 205489 / IND 109108**
**COTEMPLA XR-ODT (methylphenidate) extended release orally disintegrating tablets**
**SN 0260**

Dear Dr. Farchione,

Neos Therapeutics (Neos) was acquired by Aytu BioPharma in March of 2021. Neos Therapeutics is a fully owned subsidiary of Aytu BioPharma; therefore, communications and contacts will remain under the Neos Therapeutics name.

Reference is made the approved New Drug Application (NDA) 204326 for Cotempla XR-ODT (methylphenidate) extended-release orally disintegrating tablets approved on June 19, 2017. Neos Therapeutics would like to submit the response to the Notification of Non-Compliance with PREA received on March 27, 2024.

In support of this response, Neos has provided the following:

1-17-2-correspondence-regarding-postmarket-requirements

Should you have any questions or require additional information, please contact me by phone at 972-408-1301 or email at lvasquez@aytubio.com.

Sincerely,

Lilly Vasquez

Digitally signed by Lilly Vasquez
Date: 2024.05.24 10:40:55 -05'00'

Lilly Vasquez
Regulatory Affairs Manager

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