9 February 2021

Mitchell V. Mathis, M.D.
CAPT USPHS
Director, Division of Psychiatry Products
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration
Central Document Room
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

Updated Phase IV Protocol and Proposed Schedule

RE: NDA 204326
Adzenys XR-ODT (Amphetamine Extended Release Orally Disintegrating Tablets)
Sequence Number 0179

Dear Dr. Mathis:

As per the Type C meeting written responses received from the Division regarding the PMR requirements for Adzenys XR-ODT, Neos has provided a revised Phase IV protocol addressing the FDA comments and a proposed Phase IV study schedule as requested by the Division.

Should you have questions regarding this submission or require additional information, please contact me by phone 703-577-8291 or e-mail regulatory_email_forwarding@neostx.com.

Sincerely,

Dana Dunn
Digitally signed by Dana Dunn
Date: 2021.02.10 08:19:14 -05'00'

Dana Dunn
Dunn Regulatory Associates, LLC

1.11.3 Clinical Information Amendment

As per the Type C meeting written responses received from the Division regarding the PMR requirements for Adzenys XR-ODT, Neos has provided a revised protocol addressing the FDA comments and a proposed Phase IV study schedule as requested by the Division. In addition, Neos is proposing the following schedule for the new Phase IV PMR timeline:

Final Protocol Submission Date:	February 10, 2021
Study completion:	September 2025
Final Study Report Submission:	March 2026

These proposed timelines were based on regulatory precedence and impact on clinical trial recruitment during the pandemic. The timelines are consistent with the Phase IV study timelines for Adhansia XR® (methylphenidate HCl) extended-release capsules as outlined in their approval letter. In addition, the proposed timelines reflect the ongoing impact from COVID-19 on clinical studies generally and on the difficulties in recruiting in the 4-6 year old patient population specifically. Based on discussions with our planned CRO for this study, Neos has learned that clinical study enrollment continues to be negatively impacted by COVID-19. Specifically, there are fewer subjects making themselves available for clinical studies, particularly where such studies require in-person visits for collection of study data such as vital signs and blood work. Given the current environment and the pace of COVID-19 vaccinations, it is not clear when the negative impact on study enrollments will abate.

In conclusion, it is the opinion of the Sponsor that it has adequately addressed the Division's feedback on the design of the Phase IV protocol and that the proposed timelines represent a realistic and achievable timeline for completion on the trial based on previous regulatory precedence and clinical trial logistics in this patient population.