

**RESPONSE TO PREA NON-COMPLIANCE LETTER**  
**DEFERRAL EXTENSION REQUEST**



August 18, 2020

Tiffany Farchione MD  
Acting Division Director  
Division of Psychiatry  
FDA, CDER  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

NDA 204326, Serial # 0163  
IND 112,991, Serial # 0052

Dear Dr. Farchione:

This letter is in response to a PREA deficiency letter received by Neos Therapeutics (NEOS) dated July 28, 2020 regarding postmarketing commitments (PMRs) for Adzenys XR-ODT. At this time, the Sponsor is requesting a PREA deferral for the following reasons:

- In June 2019, the Sponsor met with the Division to discuss the design and timing of the PMRs for the following studies:
  - **3029-2 A randomized, double-blind, placebo-controlled, flexible-dose titration study of ADZENYS XR-ODT (amphetamine extended-release orally disintegrating tablets), in children ages 4 to 5 years diagnosed with ADHD.**
    - n= (b) (4)  
Final Protocol Submission: May 2017  
Study Completion: July 2020  
Final Report Submission: November 2020
  - **3029-3 A one year pediatric open-label safety study of patients age 4 to 5 years (at the time of entry into PMR 3029-1 or PMR 3029-2, or at the time of enrollment if directly enrolled into PMR 3029-3)**

**diagnosed with ADHD treated with ADZENYS XR-ODT (amphetamine extended-release orally disintegrating tablets).**

- Extension study to 3029-2  
Final Protocol Submission: May 2017  
Study Completion: July 2021  
Report Submission: November 2021

At this meeting, the Division agreed that:

1. Neos could utilize PK modeling to extrapolate the efficacious dose;
2. PMR studies 3029-2 and 3029-3 could be combined into a single study;  
and
3. Neos should re-engage with Division to discuss the results of the PK modeling and simulation in 4 to 5-year olds prior to implementation of the study.

Neos has completed the PK modeling requested by the Division; and plans to re-engage the Division through a Type C meeting once Face to Face (F2F) meetings are being granted by the FDA. It is the opinion of the Sponsor that a F2F meeting is the optimal venue to agree on the protocol design and timing. A [copy of the minutes](#) from the June 2019 meeting is attached for your convenience.

- The COVID-19 pandemic has made it impossible to implement PMR studies in children 4 to 5 years old.

For these reasons, Neos is requesting a deferral from all PMR requirements (PREA) related to Adzenys XR-ODT until 2024.

If you have any questions or concerns about this request, please contact me at [ddunn@dunnregulatory.com](mailto:ddunn@dunnregulatory.com) or via phone at (703) 577-8291.

Sincerely,

Dana  
Dunn  
Dana Dunn, MS  
Regulatory Consultant to Neos  
Dunn Regulatory Associates, LLC  
2709 Silkwood Ct  
Oakton, VA 22124

Digitally signed by  
Dana Dunn  
Date: 2020.08.18  
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