



NDA 204326/S-012

**APPROVAL LETTER**

Neos Therapeutics Brands, LLC  
Attention: Lilly Vasquez  
Regulatory Affairs Senior Manager  
7900 E. Union Ave., Suite 920  
Denver, CO 80237

Dear Lilly Vasquez:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 15, 2023, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets.

This “Changes Being Effected in 30 days” supplemental new drug application provides for changes to the printing on the blister packaging for ADZENYS XR-ODT.

**APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

**CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on December 21, 2023, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 204326/S-012.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teshara G. Bouie, Senior Regulatory Business Process Manager, at (301) 796 - 1649.

Sincerely,

*{See appended electronic signature page}*

Vilayat Sayeed, Ph.D.  
Director  
Division of Product Quality Assessment II  
Office of Product Quality Assessment I  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling



Vilayat  
Sayeed

Digitally signed by Vilayat Sayeed

Date: 3/28/2025 07:19:42AM

GUID: 508da70600028a7aad41a1cc455d8261