



NDA 205489/S-016

APPROVAL LETTER

Neos Therapeutics Brands, LLC
Attention: Lilly Vasquez, Regulatory Affairs Manager
2940 N. Highway 360
Suite 400
Grand Prairie, TX 75050

Dear Ms. Vasquez:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 12, 2023, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cotempla XR-ODT (methylphenidate extended-release orally disintegrating tablets).

This “Changes Being Effectuated” supplemental new drug application provides for changes to the excipient specification and testing to reflect the current USP monograph for Polyethylene Glycol 3350 (USP) used in the drug product manufacturing.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and Medication Guide) with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 February 9, 2024, 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 205489/S-016.**” 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}

Gurpreet Gill-Sangha, Ph.D., Supervisor
Division of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling
Carton and Container Labeling



Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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