NDA 208147/S-012; NDA 210526/S-001

SUPPLEMENT APPROVAL

Tris Pharma, Inc.
Attention: Norma J. Cappetti
SVP of Regulatory Affairs
2033 Route 130, Suite D
Monmouth Junction, NJ 08852

Dear Ms. Cappetti:

Please refer to your supplemental New Drug Application(s) (sNDA) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), and all amendments, for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 208147/S-012	DYANAVEL XR (amphetamine) Extended-Release Oral Suspension (eq. 2.5 mg amphetamine base per mL)	December 14, 2021	December 14, 2021
NDA 210526/S-001	DYANAVEL XR (amphetamine) Extended-Release Tablets, 5 mg, 10 mg, 15 mg and 20 mg	December 14, 2021	December 14, 2021

These "Changes Being Effected" supplemental new drug applications provide for revised prescribing information with the correction to the Description, Section 11.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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) with the addition of any labeling changes in pending "Changes Being Effected" (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/Drugs/GuidanceComplianceRegulatoryInformation/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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kimberly Hudgens, Regulatory Business Process Manager, at (240) 402 - 4884.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Content of Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
Date: 6/01/2022 10:35:28AM
GUID: 5135f2ad000117842392c50c36c7f28a