DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 91601

Tris Pharma, Inc.
Attention: W. Scott Groner
Director, Regulatory Affairs and Compliance
2033 Route 130
Monmouth Junction, NJ 08852

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 30, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Methylphenidate Hydrochloride Oral Solution, 5 mg/5 mL and 10 mg/5 mL.

Reference is also made to your amendments dated July 7, and December 9, 2009; and March 31, April 14, April 15, April 30, June 18, and July 9, 2010.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Methylphenidate Hydrochloride Oral Solution, 5 mg/5 mL and 10 mg/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Methylin Oral Solution, 5 mg/5 mL and 10 mg/5 mL, respectively, of Mallinckrodt, Inc.

The reference listed drug (RLD) upon which you have based your ANDA, Methylin Oral Solution, 5 mg/5 mL and 10 mg/5 mL, of Mallinckrodt, Inc. (Mallinckrodt), is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”), U.S. Patent No. 7,691,880 (the '880 patent), is scheduled to expire on October 7, 2024.

Your ANDA contains a paragraph IV certification to the '880 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Methylphenidate Hydrochloride Oral Solution, 5 mg/5 mL and 10 mg/5 mL, under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Tris Pharma, Inc. (Tris) for infringement of the listed '880 patent. This action must have been brought against Tris prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Tris complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Tris within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, the agency has determined that Tris was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '880 patent. Therefore, with this approval, Tris is eligible for 180-days of generic drug exclusivity for Methylin Oral Solution, 5 mg/5 mL and 10 mg/5 mL. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with

applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-91601	ORIG-1	TRIS PHARMA INC	METHYLPHENIDATE HYDROCHLORIDE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

07/23/2010

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.