DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091135

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 9, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dextromethorphan Polistirex Extended-release Oral Suspension, (equivalent to Dextromethorphan Hydrobromide, 30 mg/5 mL) (OTC).

Reference is made to the tentative approval letter issued by this office on April 20, 2011, and to your amendments dated August 3, August 11, and November 11, 2011.

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 over-the-counter (OTC) 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 Dextromethorphan Polistirex Extended-release Oral Suspension, (equivalent to Dextromethorphan Hydrobromide, 30 mg/5 mL), to be bioequivalent to the reference listed drug product (RLD) Delsym Extended-release Cough Suppressant, 30 mg/5 mL, of Reckitt Benckiser. As noted in our communication dated July 28, 2011, your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, Delsym Cough Suppressant of Reckitt Benckiser, 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. 5,980,882 (the '882 patent), is scheduled to expire on April 16, 2017.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the ‘882 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Dextromethorphan Polistirex Extended-release Oral Suspension, 30 mg/5 mL, under this ANDA. You have notified the agency that Tris Pharma, Inc. (Tris) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Tris for infringement of the '882 patent within the statutory 45-day period in the United States District Court for the District of New Jersey [Reckitt Benckiser Inc. and UCB Manufacturing, Inc. v. Tris Pharma, Inc., Civil Action No. 09-cv-03125]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, expired In addition, you have informed the agency that on December 21, 2011, the United States District Court granted Tris Pharma’s motion for summary judgment.

With respect to 180-day generic drug exclusivity, we note that Tris was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '882 patent. Therefore, with this approval, Tris is eligible for 180-days of generic drug exclusivity for Dextromethorphan Polistirex Extended-release Oral Suspension, 30 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.

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.

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

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

05/25/2012

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