DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-514 / S-001

Shire Pharmaceuticals
Attention: Harris L. Rotman, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5637

Dear Dr. Rotman:

Please refer to your supplemental new drug application dated June 20, 2006, received June 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Daytrana (methylphenidate transdermal system).

This "Changes Being Effected" supplemental new drug application provides for changes in the product labeling as requested in the Division's letter of May 22, 2006.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the submitted labeling text (copy attached). The final printed labeling (FPL) must be identical to the submitted labeling (package insert and patient package insert submitted June 20, 2006).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-514/S-001**." 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 (21 CFR 314.80 and 314.81).

If you have any questions, email LT Felecia Curtis, RN, Regulatory Project Manager, at Felecia.Curtis@HHS.FDA.GOV.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure (labeling)

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

/s/

Thomas Laughren
7/27/2006 01:58:37 PM