DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21514/S-008 **SUPPLEMENT APPROVAL**
FULFILLMENT OF POSTMARKETING COMMITMENTS

Shire Development, Inc.
Attention: James Ewing
Manager, Global Regulatory Affairs
725 Chesterbrook Blvd
Wayne, PA 19087-5637

Dear Mr. Ewing:

Please refer to your supplemental new drug application dated and received February 29, 2008, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Daytrana (methylphenidate transdermal system) 10mg/12.5cm^2, 15mg/18.75cm^2, 20mg/25 cm^2, 30mg/37.5 cm^2.

We acknowledge receipt of your amendments dated March 14, 2008, August 28, 2008, and November 19, 2008.

This "Prior Approval" supplemental new drug application proposes the following revisions to product labeling:

- Addition of the following paragraph to **WARNINGS – Contact Sensitization** and **ADVERSE REACTIONS – Skin Irritation** sections of the labeling:

  In an open-label study of 305 subjects conducted to characterize dermal reactions in children with ADHD treated with Daytrana™ using a 9-hour wear time, one subject (0.3%) was confirmed by patch testing to be sensitized to methylphenidate (allergic contact dermatitis). This subject experienced erythema and edema at Daytrana™ application sites with concurrent urticarial lesions on the abdomen and legs resulting in treatment discontinuation. This subject was not transitioned to oral methylphenidate

- Addition of the following sentence to "**What are possible side effects of Daytrana?"** section of the **Medication Guide:**

  Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit 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/ucm155657.htm that is identical to the enclosed agreed-upon labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **SPL for approved sNDA 21-514/S-008.**

POSTMARKETING COMMITMENTS

Your submission reported on the following postmarketing study commitment as delineated in our Agency letter dated April 6, 2006:

Commitment #1218-2	Contact sensitization study for estimating the risk of sensitization in a clinical setting.

We have reviewed your submission and conclude that the above commitment was fulfilled.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Shin-Ye Sandy Chang, Regulatory Project Manager, at (301) 796-3971.

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
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21514	SUPPL-8	SHIRE DEVELOPMENT INC	Daytrana System

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

/s/

THOMAS P LAUGHREN
12/14/2009