DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-078/S-042

GlaxoSmith Kline
Attention: Maria Wagner, Ph.D.
Senior Director, US Regulatory Affairs, Psychiatry
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Dr. Wagner:

We acknowledge receipt of your supplemental new drug application dated April 9, 2007, received April 9, 2007, and amended on April 25, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dexedrine (dextroamphetamine sulfate) Spansule Sustained-Release Capsules.

Reference is also made to an Agency letter dated February 21, 2007 and March 19, 2007 (electronic communication), requesting Medication Guides for all CNS stimulant products to treat Attention-Deficit Hyperactivity Disorder (ADHD).

Your April 9, 2007 submission provides for a response to our February 21, 2007 and March 19, 2007 requests.

This supplement, submitted under "Changes Being Effected", provides for revisions to the "**PRECAUTIONS-Information for Patients**" section to reference the Medication Guide, a revised package insert incorporating the new Medication Guide in place of the patient information leaflet, and revised container labeling for each strength of Dexedrine instructing the authorized dispenser to provide a Medication Guide to each patient that receives a prescription for the product.

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 enclosed labeling text.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, contact LT Felecia Curtis, Regulatory Project Manager, at (301) 796-0877.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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
5/1/2007 02:02:41 PM