DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-078/S-044

GlaxoSmithKline
Attention: Maria Wagner, Ph.D.
Senior Director, Psychiatry and Neurology
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. Wagner:

We acknowledge receipt of your supplemental new drug applications dated July 13, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dexedrine (dextroamphetamine sulfate) spansule sustained-release capsules and tablets.

This "Prior Approval" supplemental new drug application provides for revisions to the **Description**, **Indications and Usage**, **Precautions**, **Dosage and Administration**, and **How Supplied** sections providing for the deletion of the 5 mg tablets.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the enclosed final printed labeling (FPL) submitted on July 13, 2007.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Nicholette Hemingway, Regulatory Project Manager, at (301) 796-1365.

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

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
5/23/2008 09:51:20 AM