



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-078/S-040

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 February 23, 2006, received February 24, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dexedrine (dextroamphetamine sulfate) Spansule Sustained-Release Capsules and Tablets.

Reference is also made to an Agency action letter on the above application dated May 22, 2006.

We acknowledge receipt of your submissions dated May 19, 2006 and June 21, 2006.

Your submission dated June 21, 2006 constituted a complete response to our May 22, 2006 letter.

This "Changes Being Effected" supplemental new drug application provides for the following CNS stimulant class labeling revisions as requested in our May 22, 2006 letter:

- To include additional text in the **Boxed Warning** and **WARNINGS** section of the package insert.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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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 Felicia Curtis, Regulatory Project Manager, at (301) 796-0877.

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
8/10/2006 08:26:51 AM