DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-121/S-014

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Ann M. Jenkins-Frison
Associate Director, Global Regulatory Affairs
1125 Trenton-Harbourton Road, P.O. Box 200
Titusville, NJ 08560-0200

Dear Ms. Jenkins-Frison:

We acknowledge receipt of your supplemental new drug application dated April 9, 2007, and amended on April 17, 2007 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Concerta (methylphenidate hydrochloride) Extended-Release Tablets.

We also refer to Agency communications dated February 21, 2007, and March 19, 2007.

This supplement, submitted under "Changes Being Effected", provides for revisions to the **PRECAUTIONS-Information for Patients** section of labeling, revised container labeling in accordance with 21 CFR 208, and a Medication Guide which supersedes your current patient package insert as requested in our February 21, 2007, and March 19, 2007 communications.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

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 LT Felecia Curtis, Regulatory Project Manager, at 301-796-1074.

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
5/3/2007 09:11:19 AM