DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-121/S-015/S-017

Johnson and Johnson Pharmaceutical Research &
Development, L.L.C
Attention: Ann Jenkins-Frison
Associate Director, Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Dear Ms Jenkins-Frison:

Please refer to your supplemental new drug applications dated May 17, 2007 (S-015) and August 29, 2007 (S-017), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Concerta (methylphenidate HCl) Extended-Release tablets.

We acknowledge receipt of your submissions submitted to S-017 dated December 6, and 21, 2007, February 8, 2008, February 29, 2008, March 13, 2008, June 5, 2008, June 19, 2008 and June 24, and 25, 2008.

These supplemental new drug applications provide for the following revisions to product labeling:

S-015

- Revisions to the Adverse Reactions-Post-Marketing Experience section.

S-017

- Provides for the use of Concerta (methylphenidate HCl) tablets for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults (18 years and older).

We have completed our review of these applications, as amended. They are approved effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. You are also responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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/oc/datacouncil/spl.html that is identical to the enclosed 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 supplements 21-121/S-015/S-017.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. Clinical trials in the pediatric population have been performed in children 6 years of age and older, and Concerta is adequately labeled for use in the pediatric population. We are waiving pediatric studies in children under 6 years of age because it is difficult to diagnose ADHD in this age group. Therefore, no additional studies are needed in this pediatric group.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this the Division of Psychiatry Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
HFD-001, Suite 5100
5515 Security Lane
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, call CDR 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
6/27/2008 09:08:44 AM