DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021121/S-022 **SUPPLEMENT APPROVAL**

Johnson & Johnson Pharmaceutical Research & Development
Attention: Christine Grundy, Pharm.D.
Manager, Regulatory Affairs
920 U.S. Highway Route 202
P.O. Box 300
Raritan, NJ 08869-0602

Dear Dr. Grundy:

Please refer to your supplemental new drug application dated and received December 22, 2008, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Concerta (methylphenidate HCL) Extended-Release tablet 18mg, 27mg, 36mg, and 54mg.

We additionally reference an Agency letter dated January 13, 2009, informing you that the user fee for this application was received by the Office of Financial Management on January 8, 2009.

We acknowledge receipt of your submissions dated February 9, 2009; March 4, 11, 17, 2009; September 15, 2009; October 22, 27, 2009.

This "Prior Approval" supplemental new drug application proposes the following changes:

Section 9.2 (Drug Abuse and Dependence, Subsection Abuse), the addition of information regarding abuse potential of CONCERTA versus immediate-release methylphenidate; Section 9.4 (Drug Abuse and Dependence, Subsection Human Data), has been deleted and moved to Section 9.2.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

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)(1)(i)] 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 for the package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 021121/S-022".

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

Please submit one market package of the drug product when it is available.

LETTERS TO HEALTH CARE PROFESSIONALS

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
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Shin-Ye Sandy Chang, Regulatory Project Manager, at (301) 796-3971.

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
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21121	SUPPL-22	ORTHO MCNEIL JANSSEN PHARMACEUTICAL INC	CONCERTA

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
11/04/2009