DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021802/S-014/S-016 **SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation
Attention: Yifeng Jia, Ph.D.
Drug Regulatory Affairs/NSO
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Jia:

Please refer to your supplemental new drug applications dated March 31, 2009 (S-014), and June 25, 2009 (S-016), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Focalin XR (dexmethylphenidate HCL) extended-release capsules 5 mg, 10 mg, 20 mg, and 30 mg.

We acknowledge receipt of your submission dated August 24, 2009.

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

S-014 (submitted as a "Prior Approval" supplement)

- Removes the 20 mg maximum dose restriction from Focalin XR labeling.

S-016 (submitted as a "Prior Approval – CMC" supplement)

- Provides for the addition of the 30mg strength.

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 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 21802/S-014/S-016".

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

We are waiving the pediatric study requirement for ages 0 to 5 years because this product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group and is not likely to be used in a substantial number of pediatric patients in this age group. The diagnostic criteria and assessment measures for determining efficacy for the treatment of ADHD in children less than 6 years old are not well defined, and pharmaceutical treatment in this age group is uncommon

Post Marketing Commitment

Your submission reported on the following postmarketing study commitment as delineated in our Agency letter dated May 26, 2005:

Study #3: Conduct a pediatric fixed-dose response study.

We have reviewed your submission and conclude that the above commitment was fulfilled.

The following commitment(s) acknowledged in our May 26, 2005 letter are pending:

Study #1 An *in vitro* interaction study with clinically relevant alcohol concentrations is requested to examine the effect of ethanol on dose dumping. Dissolution profiles for Focalin XR should be generated with the media, containing ethanol concentrations ranging from 0% to 24% in 4% increments, (n.b. both acid and buffer phases should have the same ethanol concentration). Please note that the effect of ethanol on drug degradation should also be addressed when performing these experiments. - *(final report submitted 05/09/07)*

Study #2 A thorough QT study examining relevant doses in adults is required. – *(final report submitted 07/16/07)*

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.

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-21802	PMR/PMC-1	NOVARTIS PHARMACEUTICALS CORP	FOCALIN XR CAPS

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
10/23/2009