DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021802/S-017 **SUPPLEMENT APPROVAL**

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

Dear Dr. Jia:

Please refer to your 31 March 2010 Supplemental New Drug Application (sNDA), received 31 March 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Focalin XR® (dexmethylphenidate HCL) Extended Release 5mg, 10mg, 15mg, 20mg, and 30mg Capsules.

Reference is also made to an e-mail dated February 19, 2010, from the Agency requesting safety labeling revisions based upon a Post Marketing Commitment QT /QTc study submitted to the NDA on November 9, 2009.

This Changes Being Effected supplemental new drug application provides for the addition of a new subsection under the **CLINICAL PHARMACOLOGY** section entitled **12.2 Pharmacokinetics-Effects on QT Interval**.

We have completed our review of this application. 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, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

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, email Juliette Touré, Regulatory Project Manager, at Juliette.Toure@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21802	SUPPL-17	NOVARTIS PHARMACEUTICALS CORP	Focalin XR Extended-Release capsules

---

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
05/04/2010