DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDAs 021278/S-013, 010187/S-073, 021284/S-018, 018029/S-043

SUPPLEMENT APPROVAL

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

Dear Dr. Jia:

Please refer to the following Supplemental New Drug Applications (sNDA) dated and received November 5, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA):

- NDA 021278/S-013 Focalin (dexmethylphenidate hydrochloride) 2.5mg, 5mg, and 10mg Tablets,
- NDA 010187/S-073 Ritalin (methylphenidate hydrochloride) 5mg, 10mg, 20mg Tablets,
- NDA 021284/S-018 Ritalin LA (methylphenidate hydrochloride) 10mg, 20mg, 30mg, 40mg Extended-Release Capsules, and
- NDA 018029/S-043 Ritalin SR (methylphenidate hydrochloride) 20mg Extended-Release Tablet.

Reference is also made to an Agency communication requesting revisions to your proposed labeling, and your agreement submitted in your amendments dated November 24, 2010 and email dated November 30, 2010.

These Prior Approval supplemental new drug applications provide for the addition of a new subsection entitled **Effects on QT Interval** under the **CLINICAL PHARMACOLOGY** section.

We have completed our review of these supplemental 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, 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) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any annual reportable changes not included in the enclosed labeling. 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 your 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

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
12/09/2010