DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 21278/S-011/S-019
NDA 21802/S-019/S-029

SUPPLEMENT APPROVAL

Novartis Pharmaceutical Corporation
Attention: Dakshina Reddy
Global Program Regulatory Manager
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Reddy:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received on May 21, 2010 (NDA 21278/S-011 and NDA 21802/S-019), and March 7, 2014 (NDA 21278/S-019 and NDA 21802/S-029), and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Focalin (dexmethylphenidate hydrochloride) 2.5mg, 5mg, and 10mg tablets (NDA 21278/S-011/S-019) and Focalin XR (dexmethylphenidate hydrochloride) 5mg, 10mg, 15mg, 20mg, 25mg, 30mg, 35mg and 40mg extended-release capsules (NDA 21802/S-019/S-029).

We acknowledge receipt of your amendment dated January 14, 2014, for NDA 21278/S-011 and NDA 21802/S-019, which constituted a complete response to our January 14, 2013, action letter.

These Prior Approval supplemental new drug applications provide for:

- NDA 21278/S-011: Conversion of the prescribing information to the Physician's Labeling Rule (PLR) format;
- NDA 21802/S-019: Revisions to the PLR format;
- NDA 21802/S-029; NDA 21278/S-019: Updates to the Carcinogenesis/ Mutagenesis/Impairment of Fertility and Pregnancy sections of the prescribing information.

APPROVAL & LABELING

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.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as 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 that include labeling changes 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Simran Parihar, PharmD, Regulatory Project Manager, at Simran.parihar@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Prescribing Information
Medication Guide

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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01/10/2019 12:32:34 PM
On behalf of Mitch Mathis