



NDA 21284/S-020

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Susan Kummerer
Global Program Regulatory Director
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Kummerer:

Please refer to your Supplemental New Drug Application (sNDA) dated and received, March 15, 2012 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ritalin LA 10mg, 20mg, 30mg, and 40mg Capsules.

We acknowledge receipt of your amendment dated June 29, 2012.

Reference is also made to an Agency letter dated August 17, 2011, requesting that you conduct an adequate *in vitro* performance study to assess Ritalin LA in alcohol and submit proposed labeling as a labeling supplement incorporating the results of the study.

This "Prior Approval" supplemental new drug application proposes revisions to the **PHARMACOKINETICS, PRECAUTIONS, DOSAGE AND ADMINISTRATION, & MEDICATION GUIDE** sections of the U.S. prescribing information for Ritalin LA.

We have completed our review of this supplemental 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, submit the content of labeling [21 CFR 314.50(1)] 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 package insert, text for the patient package insert, 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 includes 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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).

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, contact LCDR Hiren Patel, Pharm.D, M.S, RAC, Regulatory Project Manager, at Hiren.Patel@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
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/

MITCHELL V Mathis
05/06/2013