



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022192/S-005/S-006

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Sara Kessler, MBA
Drug Regulatory Affairs – Neuroscience
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Kessler:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received May 5, 2011 (S-005), and June 10, 2011 (S-006), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fanapt (iloperidone) oral tablets 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg.

S-005

This “Prior Approval” supplemental new drug application provides for revisions to sections 12.3 (Pharmacokinetics) & 13.1 (Carcinogenesis) as requested in an Agency supplement request letter dated April 22, 2011.

S-006

This “Changes Being Effected” supplemental new drug application provides for the addition of a new Post Marketing Experience subsection, 6.2.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter. The agreed-upon labeling is attached.

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 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 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 questions, call Kimberly Updegraff, M.S., Senior Regulatory Project Manager, at (301)796-2201.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
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/

THOMAS P LAUGHREN
09/07/2011