DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022192/S-001

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Michelle Price McKern, Ph.D.
Regional Brand Regulatory Manager
Drug Regulatory Affairs – Neuroscience
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. McKern:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on June 21, 2010, 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.

This "Changes Being Effected" supplemental new drug application provides for additional information regarding poor metabolizers of CYP2D6 to be incorporated into the Highlights Section, Section 2.2 (Dosage in Special Populations) and Section 12.3 (Pharmacokinetics) as requested in our Agency letter dated May 24, 2010.

We have completed our review of this supplemental 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 include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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.

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 CDERMedWatchSafetyAlerts@fda.hhs.gov, and 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, please call Kimberly Updegraff, M.S., Senior Regulatory Project Manager, at (301)796-2201.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22192	SUPPL-1	VANDA PHARMACEUTICALS INC	Fanapt

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
08/24/2010