DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-278/S-004/S-005

Novartis Pharmaceuticals Corporation
Attention: Mara Stiles
Senior Associate Director
Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mrs. Stiles:

Please refer to your supplemental new drug applications dated November 18, 2005 (21-278/S-004), and March 24, 2006 (21-278/S-005), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Focalin (dexmethylphenidate hydrochloride) Tablets.

Reference is also made to an Agency action letter dated May 22, 2006, and an e-mail communication dated May 26, 2006.

Your submission dated June 22, 2006 constituted a complete response to our May 22, 2006 letter.

These "Changes Being Effected" supplemental new drug applications provide for CNS stimulant class labeling revisions to strengthen the wording in the **WARNINGS** section with regard to serious cardiovascular events and psychiatric events as requested in our May 22, 2006 letter.

We note that you have also updated the patient package insert (PPI) so that it is in alignment with the class labeling revisions. Although this is acceptable, at this time, we intend to request a Medication Guide in the near future for all of the CNS stimulants. The Medication Guide will then replace the PPI.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Felicia Curtis, Regulatory Project Manager, at (301) 796-0877.

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Laughren
8/24/2006 03:17:40 PM