DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-200/S-010

Novartis Pharmaceuticals Corporation
Attention: Vishwas Ganu, Ph.D.
Global Regulatory CMC
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Ganu:

Please refer to your supplemental new drug application dated November 30, 2004, received December 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zelnorm® (tegaserod) Tablets.

This "Changes Being Effected" supplemental new drug application provides for an alternate site for manufacture and analytical testing for the 2 mg tablets.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted November 30, 2005). Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-200/S-010." Approval of this submission by FDA is not required before the labeling is used.

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 Susan Daugherty, Regulatory Health Project Manager, at (301) 827-7456.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and
Coagulation Drug Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Liang Zhou

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