DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-200/S-012

Novartis Pharmaceutical Corporation
Attention: Robert Clark
U.S. Regulatory Advisor
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Clark:

Please refer to your supplemental new drug application dated December 1, 2005, received December 2, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zelnorm® (tegaserod) Tablets.

We acknowledge receipt of your submission dated April 26, 2006.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate facility for the manufacture of the 6 mg tablets.

We completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the 6 mg sample carton, 6 mg blister container, and 6 mg immediate container submitted on December 1, 2005.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Postmarketing Evaluation
Office of New Drug Quality Assessment
Center of Drug Evaluation and Research

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

/s/

Eric Duffy

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