DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 21-200/S-006

Novartis Pharmaceuticals Corporation
Attention: Joan A. Materna
Global Regulatory CMC
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Materna:

Please refer to your supplemental new drug application dated December 12, 2003 (received December 15, 2003), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zelnorm®(tegaserod maleate) Tablets.

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days", provides for a new manufacturing site for the drug product, a dissolution comparison of the drug product from the two sites, and labeling changes.

We have completed the review of this supplemental application and it is approved.

Please submit final printed labeling (FPL) identical to the enclosed labeling and immediate container and carton labels, submitted December 12, 2003.

The electronic labeling rule published December 11, 2003 (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e. package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. Approval of this submission by FDA is not required before the labeling is used.

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 Paul E. Levine, Jr., R.Ph., J.D., Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and Coagulation Drug Products, (HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Liang Zhou

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