DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-200/S-009

Novartis Pharmaceuticals Corporation
Attention: John R. Cutt, Ph.D.
Associate Director Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Cutt:

Please refer to your supplemental new drug application dated March 03, 2004 (received March 04, 2004), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zelnorm®(tegaserod maleate) Tablets.

We also refer to your submissions dated April 09 and 15, 2004; and to our meeting and telephone conferences dated March 24, and April 01, 05, and 13, 2004.

This supplemental application proposes revised labeling to provide adequate information for the safe and effective use of Zelnorm®. These changes include a WARNINGS section in the label, revisions to the PRECAUTIONS, ADVERSE REACTIONS, and **Information for the Patient** sections of the label, and a "Dear Healthcare Professional" letter that informs physicians about the serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

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

We remind you of your commitment in your submission dated April 15, 2004. This commitment is provided below.

> To submit, as Postmarketing 15-day Safety Reports, any serious adverse event as defined in Title 21 CFR 314.80, either labeled or unlabeled, related to gastrointestinal (including ischemic colitis, other forms of intestinal ischemia, and surgeries), reproductive/urinary (including pelvic surgeries), hepatobiliary (including cholecystectomies), thromboembolic disorders, or diarrhea with related syncope, hypotension, hypovolemia, or fluid replacement.

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}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Attachment:

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

/s/

Robert Justice

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