



NDA 21-200/S-014

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

Dear Ms. Larussa-Goepel:

Please refer to your supplemental new drug application dated August 31, 2006, received September 5, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zelnorm<sup>®</sup> (tegaserod) Tablets.

We acknowledge your teleconference regarding your submission on February 28, 2007.

This "Changes Being Effected" supplemental new drug application provides for the addition of elevation in ALT, AST and bilirubin, hepatitis, and alopecia to the **ADVERSE REACTIONS - Postmarketing Experience** section of the package insert.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (see attached labeling).

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-200/S-014.**" Approval of this submission by FDA is not required before the labeling is used.

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  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

NDA 21-200/S-014

Page 2

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 Cristi Stark, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D., M.P.H.  
Deputy Director  
Division of Gastroenterology Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Joyce Korvick  
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