DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Elizabeth Barbehenn, Ph.D., Research Analyst
Peter Lurie, M.D., M.P.H., Deputy Director
Sidney M. Wolfe, M.D., Director
Public Citizen's Health Research Group
1600 20th Street, N.W.
Washington, D.C. 20009

Docket No. 01P-0259/CP1

Dear Drs. Barbehenn, Lurie, and Wolfe:

This letter responds to your petition dated March 22, 2001, asking the Food and Drug Administration (FDA) not to approve Novartis' new drug application for tegaserod (Zelnorm[1]) for the treatment of constipation-predominant irritable bowel syndrome. Your petition states that you are making this request because the effectiveness of the drug is questionable and you have serious safety concerns about it.

As Novartis announced in a press release dated June 18, 2001, FDA recently refused to approve Zelnorm. Therefore, your petition is granted.

Sincerely yours,

FOR Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Enclosure

[1] The petition refers to the brand name of the drug as Zelmac; however, Novartis has changed the name to Zelnorm.

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