



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 05, 2001

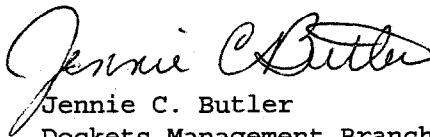
Elizabeth Barbenhenn, PhD
Peter Lurie MD MPH
Sidney M Wolfe, MD
Public Citizen Health Research Group
1600 20th Street NW
Washington, DC 20009-1001

Dear Drs. Barbenhenn, Lurie & Wolfe:

Your petition requesting the Food and Drug Administration to refuse to approve tegaserod (Zelmac) was received by this office on 05/29/01. It was assigned docket number 01P-0259/CP 1 and it was filed on 06/05/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,


Jennie C. Butler
Dockets Management Branch

01P-0259

ACK 1