



September 12, 2013

Sidney Wolfe, M.D.  
Founder, Senior Adviser  
Public Citizen's Health Research Group  
1600 20<sup>th</sup> Street, NW  
Washington, D.C. 20009

Dear Dr. Wolfe:

Your petition to the Food and Drug Administration on behalf of more than 300,000 members and supporters nationwide, and Neil A. Holtzman, M.D., for the Agency to immediately add a black-box warning on clopidogrel (brand name: Plavix, as well as generic equivalents), was received by this office on 08/22/2013. It was assigned docket number FDA-2013-P-1056/CP1, and it was filed on 08/22/2013. 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,

Karen Kennard  
Director  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)