



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

September 12, 2013

Sidney Wolfe, M.D.
Founder, Senior Adviser
Public Citizen's Health Research Group
1600 20th 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,

A handwritten signature in cursive script that reads "Karen Kennard".

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