DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 18 2014

Sidney Wolfe, M.D.
Public Citizen
1600 20th Street NW
Washington, DC 20009

Re: Docket No. FDA-2013-P-1056

Dear Dr. Wolfe:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 22, 2013. Your petition requests that the Agency immediately add a "black-box warning" on clopidogrel noting the risks of major and minor bleeding with use beyond 12 months following implantation of a drug-eluting coronary stent. You also request that FDA require an updated Medication Guide containing the information in your proposed boxed warning to be dispensed to all patients taking clopidogrel, and you request that FDA ask manufacturers to send a "Dear Doctor" letter to warn physicians of the potential adverse events identified in your proposed boxed warning.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research