DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

February 5, 2014

Michael Carome, M.D., Director
Sammy Almashat, M.D., M.P.H., Researcher
Sidney Wolfe, M.D., Founder and Senior Advisor
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Dear Drs. Carome, Almashat, and Wolfe,

Thank you for your letter of January 29, 2014 to Drs. Woodcock and Stockbridge, in which you raise concerns regarding new drug application (NDA) 204886 for vorapaxar sulfate (Zonitivity).

As you are aware, we cannot discuss the details of a pending marketing application or investigational new drug application (IND) based on several federal statutes and regulations, including the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), and FDA regulations (21 CFR 20.61(c); 21 CFR 312.130(b); 21 CFR 314.430(c) and (d)(1)). There are limited exceptions to these restrictions on FDA's discussion of a pending application or IND. For example, the Agency may disclose a summary of safety or effectiveness data, if appropriate, at an Advisory Committee meeting (21 CFR 314.430(d)(1)); it may disclose certain information when a sponsor provides a written authorization permitting FDA to disclose non-public information about its pending application or IND, and it may disclose information to the extent the sponsor itself has publicly disclosed the information.

As you know and reference in your letter, information related to this product was discussed at the January 15, 2014 meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC). We appreciate the Public Citizen's Health Research Group testimony presented at that meeting.

We note your concerns regarding vorapaxar sulfate, notably your recommendations that, if marketing approval were granted for vorapaxar, FDA should require the approved drug label to include a boxed warning indicating that use of the drug is contraindicated in any patient with a prior history of stroke or transient ischemic attack (TIA) or in patients with a body weight of less than 60 kilograms. You also recommend that use of vorapaxar be limited to patients with a prior history of myocardial infarction (MI), but recommend that the indication not be expanded to include patients with a history of peripheral artery disease (PAD) but no history of MI.

We will take these concerns into consideration in our evaluation process.

As always, thank you for sharing your perspective with us.

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