



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring MD 20993

April 23, 2015

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

Dear Drs. Almashat, Wolfe, and Carome:

Thank you for your letter of March 31 to the Office of Prescription Drug Promotion (OPDP), with a copy to Dr. Woodcock, Director of the Center for Drug Evaluation and Research, regarding promotional activities for Farxiga, Jardiance, Invokana, Victoza, and Bydureon. These drugs are approved for the treatment of Type 2 diabetes. OPDP's mission is to protect the public health by assuring prescription drug information is truthful, balanced, and accurately communicated.

OPDP appreciates your concern. You and other consumer advocacy groups are some of the most important resources we have in monitoring promotional activities in the prescription drug market. Your information and insights assist us in our surveillance activities and help us in our pursuit of our public health mission. We thank you for your complaint and will evaluate the materials you submitted.

If you have any questions or comments, please direct your response to OPDP by facsimile at (301) 847-8444, or at the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266.

Once again, thank you for bringing this to our attention.

Sincerely

A handwritten signature in cursive script that reads "Thomas Abrams".

Thomas Abrams
Director
Office of Prescription Drug Promotion

cc: Janet Woodcock