DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 15 2012

Elizabeth Barbehenn, Ph.D.
Sidney M. Wolfe, M.D.
Public Citizen Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Re: Docket No. FDA-2012-P-0404

Dear Dr. Barbehenn and Dr. Wolfe:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on April 20, 2012. Your petition requests that the Agency immediately remove from the market the diabetes drug Victoza (liraglutide) (NDA 022341).

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 we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

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