DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

July 27, 2017

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. Almashat and Wolfe,

Thank you for your letter of July 18, 2017 to Drs. Woodcock and Guettier, in which you raise concerns regarding supplemental new drug application (sNDA) 022341 for liraglutide (Victoza) injection.

As you are aware, we cannot discuss the details of a pending marketing application or supplemental application 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, 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 June 20, 2017 meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. We appreciate the Public Citizen's Health Research Group testimony presented at that meeting.

We note your concerns regarding liraglutide, notably that this drug has not been proven effective for cardiovascular risk reduction in the U.S. population in which it was studied, and your concern that this could raise questions about the real-world effectiveness of liraglutide for reducing cardiovascular risk in U.S. diabetes patients. We will take these concerns under 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