DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

May 2, 2013

Sammy Almashat, M.D., M.P.H., Researcher
Michael A. Carome, M.D., Deputy Director
Sidney H. Wolfe, M.D., Director
Public Citizen Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Dear Drs. Almashat, Carome and Wolfe:

Thank you for your letter of April 30, 2013 to the Food and Drug Administration (FDA or Agency), in which you raise concerns regarding new drug application (NDA) 204-275 for fluticasone furoate/vilanterol (FF/VI, proposed trade name: Breo Ellipta).

As you are aware, we cannot discuss the details of a pending 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 discussing 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 April 17, 2013 meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC). We appreciate the testimony shared by the Public Citizen Health Research Group at that meeting.

We note your concerns regarding FF/VI and your opposition to FDA approval of this product, and will take those concerns into consideration in our decisional process.

Sincerely,

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research