DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

July 29, 2013

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

Dear Drs. Almashat, Barbehenn, Wolfe, and Carome,

Thank you for your letter of June 14, 2013 to the Food and Drug Administration, in which you raise concerns regarding new drug application (NDA) 204-569 for suvorexant.

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 May 22, 2013 meeting of the Peripheral and Central Nervous System (PCNS) Drugs Advisory Committee. We appreciate the Public Citizen's Health Research Group testimony presented at that meeting.

We note your concerns regarding suvorexant, and will take those concerns into consideration in our evaluation process.

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

Sincerely,

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research