U.S. FOOD & DRUG ADMINISTRATION

May 10, 2023

Nina Zeldes, Ph.D
Health Researcher
Public Citizen's Health Research Group

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

Sidney Wolfe, M.D.
Senior Advisor
Public Citizen's Health Research Group

Dear Drs. Zeldes, Carome, and Wolfe:

Thank you for your letter, dated May 3, 2023, to Dr. Califf, Commissioner of Food and Drugs, Dr. Cavazzoni, Director of FDA's Center for Drug Evaluation and Research, and Dr. Tiffany Farchione, Director of the Division of Psychiatry in the Center for Drug Evaluation and Research, urging us to reject the supplemental new drug application for brexpiprazole for the treatment of agitation associated with Alzheimer's dementia. Your letter was received by Dr. Califf and shared with the Center for Drug Evaluation and Research for response.

As you are aware, we generally cannot discuss non-public submissions or information related to ongoing drug development due to a variety of federal statutes and regulations[1]. We are aware that there has been considerable public discussion regarding this complex application, including the joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Peripheral and Central Nervous System Drugs Advisory Committee, and we recognize the critical importance of the voice of all stakeholders in this discourse.

Please know that we continuously strive to fulfill our mission of protecting and promoting public health by ensuring safe and effective drugs are available to patients.

Thank you, again, for sharing your thoughts with us regarding this matter.

Sincerely,

CDER Executive Operations

[1] Relevant laws include 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 (e.g. 21 CFR 20.61(c), 21 CFR 312.130(b), 21CFR 314.430(c), and (d)(l))).

U.S. Food & Drug Administration
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