DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

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Michael A. Carome, M.D.
Sidney Wolfe, M.D.
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Dear Drs. Aladdin, Carome, and Wolfe,

Thank you for your letter of February 27, 2019 to Dr. Gottlieb and myself, in which you raise concerns regarding New Drug Application (NDA) 211243 for esketamine (SPRAVATO) for intranasal administration for the treatment of treatment-resistant depression (TRD).

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 esketamine was discussed at the February 12, 2019 joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. We note your comments, notably your concern that data from clinical trials presented in the NDA fail to provide substantial evidence that esketamine is effective for its proposed indication, and that the applicant failed to demonstrate that esketamine has a favorable benefit-risk profile for the treatment of TRD. 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