December 19, 2022

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Medical Director, Opioid Policy Research Collaboration
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President, Physicians for Responsible Opioid Prescribing

Dear Drs. Abrams, Carome, Wolfe and Kolondy:

Thank you for your December 7, 2022, letter to Drs. Califf and Shuren regarding Public Citizen's opposition to the marketing authorization of AvertD (SOLVD Health) for identifying patients at increased risk of opioid use disorder (OUD). Your letter has been referred to the FDA's Center for Devices and Radiological Health (CDRH), Office of Product Quality and Evaluation (OPEQ), which has responsibility for the review of premarket submissions of medical devices.

Generally, for submissions referred to an Advisory Committee, the FDA considers available information pertaining to the file, including any recommendations, panel deliberations, and voting as part of its review of that premarket submission.

Please note that although advisory committees provide recommendations to the FDA, the FDA makes the final decision on whether to authorize marketing of a device in the U.S.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We hope this information is of value to you and appreciate you taking time to contact the FDA.

Sincerely,

Timothy T. Stenzel -S

Digitally signed by Timothy T. Stenzel -S
Date: 2022.12.19 12:19:27 -05'00'

Timothy T. Stenzel, MD, PhD
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