Congress of the United States

Washington, DC 20515

May 1, 2026

The Honorable Martin A. Makary, M.D., M.P.H.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Commissioner Makary:

We write regarding the U.S. Food and Drug Administration's (FDA) ongoing evaluation of rapid-acting novel therapeutics, including entactogen- and psychedelic-assisted therapies, for mental health conditions affecting millions of Americans. For many individuals, current treatment options remain insufficient, deepening an already urgent public health crisis. As Members of the House of Representatives, we have heard from countless Veterans, clinicians, and families seeking evidence-based alternatives, and many of us joined a bipartisan letter to President Biden in 2024 urging his administration to support access to MDMA-assisted therapy for post-traumatic stress disorder (PTSD), pending FDA approval.[1]

We are encouraged by your public statements recognizing these treatments as "a top priority for this FDA and this administration." We agree that the agency must conduct "an expeditious and rapid review" of promising treatments, especially those that address urgent unmet needs in PTSD, traumatic brain injury, and other neuropsychiatric conditions.[2]

At the same time, we understand and respect the agency's role in ensuring that any new treatment meets rigorous standards of safety and efficacy. Recent regulatory actions, including the issuance and public release of the Complete Response Letter (CRL) for MDMA-assisted therapy, highlight the complexity of evaluating innovative treatment modalities and underscore the need for clear, consistent expectations for this emerging field.

In that spirit, we respectfully request written responses to the following questions:

1. Special Protocol Assessment (SPA):
   How does the FDA communicate and apply any remaining data concerns beyond clearly defined primary endpoints and control conditions when pivotal trials are conducted under an SPA? Are improvements underway to make regulatory expectations more predictable for therapies in emerging fields?

2. Methodological Standards and Interagency Coordination:
   What steps is the FDA taking to clarify methodological expectations for entactogen- and psychedelic-assisted clinical trials – including strategies to mitigate functional unblinding and expectancy effects – and how is the agency coordinating with federal partners such as the U.S. Department of Veterans Affairs to streamline research pathways for populations with urgent unmet needs, including Veterans with PTSD?

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[1] Congressmen Jack Bergman, Lou Correa, Morgan Luttrell, and Jimmy Panetta to President Joseph R. Biden, Jr., letter, August 2, 2024, https://bergman.house.gov/uploadedfiles/mdma_assisted_therapy_letter.pdf.

[2] "On Balance," *NewsNation*, May 16, 2025, https://www.youtube.com/watch?v=KEQFKBME668.

3. Review Integrity and Subject-Matter Expertise:
   How does the FDA ensure that qualified experts with relevant experience conduct reviews of entactogen- and psychedelic-assisted therapies? What steps are in place to ensure consistency, objectivity, and independence in the evaluation process?

4. Final Guidance Timeline:
   What is the expected timeline for finalizing the FDA's June 2023 guidance on clinical trials involving rapid-acting novel therapeutics, including entactogen- and psychedelic-assisted therapies?[3]

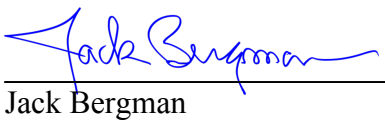
In addition, we encourage the FDA to provide further clarity in the final guidance around:

- Strategies to mitigate functional unblinding and expectancy bias;
- Standards for adverse event monitoring and safety reporting;
- Provider training, licensing, and participant safeguards;
- The evolving role of psychotherapy in conjunction with pharmacological intervention;
- Generalizability of findings across diverse patient populations; and
- Consistency in regulatory expectations across entactogen and psychedelic drug development programs.

We remain committed to ensuring that Veterans and others living with treatment-resistant mental health conditions have access to safe, evidence-based care. We respectfully urge the FDA to continue its evaluation of entactogen- and psychedelic-assisted therapies with transparency, urgency, and scientific rigor as the agency carries out its statutory responsibilities.

Thank you for your leadership and ongoing commitment to addressing this critical public health issue.

Sincerely,



Jack Bergman
Member of Congress

J. Luis Correa
Member of Congress

David G. Valadao
Member of Congress

Derek T. Tran
Member of Congress

[3] "Psychedelic Drugs: Considerations for Clinical Investigations." U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, June 9, 2023, https://www.fda.gov/media/169694/download.

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Member of Congress

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Member of Congress

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Member of Congress

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Member of Congress

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Member of Congress

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Member of Congress

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Member of Congress