Docket No. FDA-2025-N-2338
Re: Generative AI–Enabled Digital Mental Health Medical Devices

Thank you for the opportunity to comment. I submit this as Founder of AInome, a digital mental wellness research and governance initiative, and as a student specializing in AI-enabled mental health systems, Indigenous data governance, and community-defined wellness models.

1. Generative AI requires a distinct regulatory approach
   AI tools used in mental health contexts do not behave like traditional software. They are non-deterministic, context-sensitive, and capable of emergent behavior. Their outputs often appear relational or therapeutic, even when clinically inaccurate. This creates a unique risk profile that warrants tailored oversight, evidence standards, and monitoring.
2. Cultural validity is a safety issue, not an optional consideration
   Mental health communication varies significantly across cultures, languages, and histories. Indigenous, rural, and trauma-impacted communities express distress in ways generative models routinely misinterpret. Systematic misinterpretation is a foreseeable harm. FDA should require evidence that AI mental health tools are validated in diverse populations reflective of intended use.
3. High-risk psychological interactions require human escalation
   Generative AI should not autonomously respond to suicide ideation, self-harm, trauma disclosures, or violence. In these situations, incorrect reassurance or inappropriate therapeutic tone can create significant harm. Clear requirements for human oversight and escalation will align these devices with established risk-based regulatory principles.
4. Indigenous data governance must be integrated where applicable
   If AI systems interact with Indigenous users or Indigenous data, regulatory expectations should reference Indigenous data sovereignty principles. This includes community-informed consent, governance participation, and transparency regarding

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data use. These considerations strengthen safety, equity, and clarity in regulatory implementation.

5. Continuous monitoring is essential for adaptive systems
   Generative AI models evolve after deployment. FDA should require post-market monitoring for model drift, bias amplification, harmful outputs, and other emergent behaviors. Premarket evaluation alone cannot ensure ongoing safety and effectiveness.

Summary of Recommendations

1. Recognize generative AI mental health tools as a distinct regulatory class.
2. Require cultural and contextual validation for safety and effectiveness.
3. Mandate human escalation for high-risk interactions.
4. Incorporate Indigenous data governance principles when relevant.
5. Strengthen post-market surveillance requirements for adaptive models.

Conclusion

Generative AI mental health tools offer meaningful potential, but they also introduce novel and significant risks. A regulatory framework grounded in cultural validity, risk-appropriate oversight, Indigenous governance, and continuous monitoring will ensure that these technologies advance public health without compromising safety.

Thank you for your consideration.

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