KEEPING OUR PROMISE TO AMERICA'S VETERANS

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November 17, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket ID: FDA-2026-N-10429

Response of DAV (Disabled American Veterans) to the Food and Drug Administration's, Design and Safety Considerations for Clinical Trials Involving Ibogaine Drug Products; Request for Information.

DAV (Disabled American Veterans) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) and Food and Drug Administration's (FDA) request for information concerning the design of early-phase clinical trials for ibogaine drug products.

DAV is a congressionally chartered and Department of Veterans Affairs (VA)-accredited veterans service organization with nearly 1 million members. DAV helps veterans and their families obtain the healthcare and benefits they have earned, connects veterans with meaningful employment opportunities and represents their interests before Congress and the executive branch.

DAV supports rigorous, scientifically sound research into ibogaine that may address significant unmet needs among veterans to determine if using it as part of an approved course of therapy is safe or effective. Any future clinical use should depend on sufficient evidence, FDA review and approval, appropriate clinical standards, informed consent and sustained follow-up care.

Clinical research should meaningfully include veterans and account from the outset for their medical complexity, service-related conditions, geographic barriers and continuity-of-care needs.

Veterans' needs and the case for rigorous research

VA estimates that approximately 29% of Operations Iraqi Freedom and Enduring Freedom veterans will experience post-traumatic stress disorder (PTSD) in their lifetimes. Women veterans also experience higher rates of lifetime PTSD compared to female civilians. According to VA data, the lifetime prevalence of PTSD among women veterans is approximately 13% whereas the lifetime prevalence for adult women in the general civilian population is roughly 8%.

Veterans also face elevated risks associated with opioid use disorder (OUD) because of the prevalence of acute and chronic pain, mental health conditions and other social and medical stressors. Veterans living with PTSD, chronic pain, polytrauma or other co-occurring conditions therefore warrant meaningful inclusion in carefully designed research on potential treatments for substance use disorders.

There is significant evidence of demand for new treatment options for veterans seeking relief from severe or treatment-resistant conditions. For example, many have traveled abroad at significant personal expense to obtain ibogaine therapy. FDA-regulated trials provide a responsible pathway to scientifically evaluate benefits and risks while protecting participants. Coordination among FDA, VA, HHS, sponsors and qualified researchers can help ensure that this work addresses veterans' needs and informs future standards of care if the evidence supports approval.

General study design and veteran-inclusive populations

Research protocols should reflect the health profiles and practical circumstances of disabled veterans, including common comorbidities of PTSD, traumatic brain injury, polytrauma, chronic pain, cardiovascular disease, substance use disorders and polypharmacy. Eligibility criteria should protect participants without unnecessarily excluding those most likely to need new treatment options.

When scientifically appropriate, protocols should use individualized risk stratification, enhanced monitoring and specialist consultation instead of categorical exclusions for veterans with stable comorbid conditions. Sponsors should consult VA clinicians and researchers with relevant expertise when developing eligibility criteria and monitoring plans.

Trial design should seek to reduce or eliminate geographic and financial barriers by including travel and lodging assistance, telehealth-enabled prescreening and follow-up when clinically appropriate, and coordination with VA facilities and qualified research partners. These measures can improve access for rural and geographically dispersed veterans while preserving appropriate clinical and research oversight.

Research sites should use trauma-informed practices and personnel familiar with military culture, service-related trauma, moral injury and veteran mental health to strengthen trust, retention, psychological safety and safety reporting. To support these efforts, the VA offers military cultural competency training for researchers to broaden their knowledge and guide appropriate interactions with disabled veterans during clinical trials.

Veteran safety and oversight

Veteran safety must remain paramount throughout ibogaine research, with care responsive to each participant's individual needs and research conducted to the highest standards of patient safety. Veterans should be fully informed about participation and receive clear, ongoing communication throughout the research process. Transparency and independent oversight should be maintained at every stage to protect participants and sustain trust.

Psychological safety, integration and long-term follow-up
Protocols should provide structured preparation, support during administration and post-dosing integration led by qualified, trauma-informed professionals. Participants should have timely access to evaluation and treatment for psychological distress, suicidality, destabilization or other adverse effects.

Follow-up should extend beyond the immediate dosing period and should evaluate safety, symptom change, durability of any benefit, recurrence of substance use or PTSD symptoms, functional outcomes and delayed adverse events. Where legally and ethically permissible, researchers should explore appropriately authorized VA data resources and longitudinal health records to support long-term outcomes research while maintaining informed consent, privacy, data-security and research-governance requirements.

Trial designs should also recognize the role of caregivers and family members if the participant consents to have them involved. With the participant's consent, caregivers and family members should receive appropriate education about the integration period, warning signs that may require clinical attention and available support resources. Their involvement should supplement, not replace, professional follow-up care.

Ethical considerations, informed consent and protection from coercion
Veterans living with severe, chronic or treatment-resistant PTSD, chronic pain or OUD may be especially vulnerable to overstating the likelihood of benefit from an experimental intervention. Recruitment must therefore be voluntary and free from real or perceived coercion. Recruitment materials and consent discussions should clearly state that choosing not to participate will not affect a veteran's access to VA healthcare, disability compensation or other veteran benefits.

Informed consent should clearly distinguish research participation from clinical treatment and state that the investigational product's safety and effectiveness have not been established for the condition under study. Materials should use accessible language and explain known and reasonably foreseeable cardiac, neurological, psychiatric and other risks; areas of uncertainty; alternative treatment options; the possibility of no benefit; and the participant's right to withdraw.
Consent must be regarded as a process that continues, not as a one-time event. Participants should receive materials regarding new safety information as it becomes available and should have meaningful opportunities to ask questions. Protocols should include safeguards to assess decisional capacity when clinically appropriate and to manage expectations without portraying ibogaine as a cure or guaranteed solution.

Conclusion
DAV is hopeful that ibogaine may eventually expand care options for veterans whose conditions have not responded adequately to existing evidence-based treatments. Researchers must rigorously and ethically test that potential while protecting participants and producing reliable evidence.

DAV urges FDA and trial sponsors to apply the veteran-inclusive design, individualized eligibility, independent oversight, safety safeguards and sustained follow-up described above. DAV stands ready to work with FDA, HHS, VA and the research community to ensure that future studies are safe, scientifically valid and responsive to disabled veterans' needs.

Respectfully,



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