

March 26, 2010

Rick Doblin, PhD

Re: Protocol #: MP8
IRB Tracking #: [REDACTED]

"A Randomized, Triple-Blind Phase 2 Pilot Study Comparing 3 Different Doses of MDMA in conjunction with manualized psychotherapy in 16 Veterans with Chronic Posttraumatic Stress Disorder (PTSD)"

Dear Dr. Doblin,

This letter is to inform you that the above-referenced protocol application was initially reviewed by Copernicus Group IRB at the Board Meeting on February 18, 2010 and was deferred. The study was then re-submitted and re-reviewed by the fully convened Board Meeting on March 18, 2010.

Unconditional approval was granted on March 22, 2010 for the Protocol (incorporating Amendment #1, Version 2) dated 3/3/2010, the Investigator's Brochure for MDMA dated 12/2007, the MDMA-Assisted Psychotherapy for the Treatment of PTSD Revised Teaching Manual dated 11/24/2008, the Subject Information and Consent Form and Authorization to Use and Disclose Personal Health Information for Research, the Publication - "Posttraumatic growth in clinical psychology - A critical review and introduction of a two component model" dated January 2006, the Clinician Administered PTSD Scale (CAPS), the Clinician-Administered PTSD Scale for DSM-IV, Current and Lifetime Diagnostic Version (CAPS-DX), the RRPQ Scoring Form, the Wallet Card, the Case Report Forms, the Questionnaire for Long-Term Follow-up, the Informed Consent Form Quiz, the Letter from FDA dated 2/1/2010, the Posttraumatic Growth Inventory, the Beck Depression Inventory (BDI) General Information, the Beck Depression Inventory, the Subjective Units of Distress Scale, the Reminder of study rules for subjects, the Study Synopsis, the Global Assessment of Functioning General Information, the Global Assessment of Functioning Scale Guidelines, the Columbia-Suicide Severity Rating Scale (C-SSRS) Since Last Visit, the Columbia-Suicide Severity Rating Scale (C-SSRS) Baseline, the Structured Clinical Interview for DSM-IV Axis II Personality Disorders (SCID-II), the Structured Clinical Interview for DSM-IV Axis I Disorders Patient Edition (SCID-I/P), the Phone Screening Script, the Print/Internet Ad - "Are you a Veteran?...", and the Referral Letter.

Please note that CGIRB requires the reporting of any unanticipated problems involving risks to subjects or others as soon as possible, but in all cases within 5 business days in accordance with the applicable regulatory standards and CGIRB requirements.

Please do not hesitate to contact me if you need further information.