

**Michael C. Mithoefer, MD**

December 3, 2009

Re: **Study #MT-1.** “A Phase 1 Placebo-Controlled, Double-Blind Crossover Study to Assess Psychological Effects of MDMA when Administered to Healthy Volunteers”  
Amendment 2

Dear \_\_\_\_\_

I am hereby submitting a response to the deferral letter of October 26, 2009. This letter includes responses to questions posted via email immediately before and during the review period and a response to questions within the deferral letter. I am also resubmitting an amended protocol and informed consent materials for review by Copernicus Group IRB.

Please find along with this application

Response to deferral letter and response to initial questions posted to the sponsor and study PI, dated December 2, 2009

Study protocol, Amendment 2, dated December 2, 2009

Informed consent materials, dated December 1, 2009

Revised FDA form 1572, dated November 18, 2009

Copies of case report forms (CRFs) for the study, dated November 27, 2009

The latest revision of the training manual, dated November 24, 2008

Excerpts from preliminary data report, dated June 21, 2009

A copy of Johnson et al. 2008 “Human hallucinogen research guidelines for safety”, dated August, 2008


Letter of support from Matthew Johnson, dated November 17, 2009

Letter of support from Bill Richardson, dated April 6, 2009

Letter of support from Daniel Helminiak, dated April 10, 2009

Signed first page of the amended study protocol, dated December 3, 2009

Sincerely,



Michael C. Mithoefer MD