Health Canada / Santé Canada

Therapeutic Products Directorate
5th Floor, Holland Cross, Tower B
Address Locator# 3105A
OTTAWA, Ontario
K1A 0K9

SEP 0 3 2013

9427-M2544-21C

Your file *Votre référence*

Our file *Notre référence*

Amy Emerson
Director, Clinical Research
Multidisciplinary Association for Psychedelic Studies
1215 Mission St.
SANTA CRUZ, CA
95060 USA
831-429-6362

No Objection Letter RE: Amendment # 1 to Protocol # MP-4 (Version 2) and Quality Amendment

Dear Ms. Emerson:

This is to advise you that the data concerning your Clinical Trial Application for **MDMA**, control number **167090** which were received on August 8, 2013, have been reviewed and we have no objection to the amendment to the study. Please note that a new control number has been assigned to this Clinical Trial Application Amendment only. Any correspondence relating to the original CTA should be referenced to the original control number assigned. I would remind you of the necessity of complying with the *Food and Drug Regulations,* Division 5, in the sale of this product for clinical testing. In addition, the regulations impose record keeping responsibilities on those conducting clinical trials. You are also reminded that all clinical trials should be conducted in compliance with the Therapeutic Products Directorate's *Guideline for Good Clinical Practice.*

Please note that Health Canada has implemented electronic reporting of adverse drug reactions and is currently in pilots with some sponsors. Those sponsors who have an established electronic connection with Canada Vigilance Production stream should submit their reports using the distribution rules provided to them by Health Canada, and reporting to multiple directorates is no longer required. For the sponsors who have not yet established this connection, they should continue submitting their reports to the applicable directorate by fax or by courier. The following website provides further clarification on Health Canada's adverse drug reactions reporting requirements for clinical trials: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/ich/efficac/e2a_pre_notice_avis-eng.pdf

Consistent with Health Canada's Notice - *Registration and Disclosure of Clinical Trial Information* of November 30, 2007, sponsors are encouraged to register their clinical trials within 21 days of the trial's onset, using a publicly available registry that conforms with international standards for registries such as: Clinicaltrials.gov (www.clinicaltrials.gov); Current Controlled Trials (www.controlled-trials.com).

Should you have any questions concerning this letter, please contact the Office of Clinical Trials (613) 941-2132.

Yours sincerely,

Lisa Carter for

Léo Bouthillier, Ph.D.
Manager - Clinical Trials Group II
Office of Clinical Trials

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