Therapeutic Products Directorate

OUR MISSION: We contribute to the health of Canadians and to the effectiveness of the health care system by regulating pharmaceuticals and medical devices and by providing Canadians with access to information to make informed choices.

TO: Dr. Rick Doblin

Name/Nom: Dr. Rick Doblin
Organization/Organisme: Multidisciplinary Association for Psychedelic Studies
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FROM: Elizabeth Komsta, M.Sc., Ph.D.
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MESSAGE

Clinical Trials Manual/Manuel d'essais cliniques

Release of Protocol Safety and Efficacy Assessment Template—Clinical Trial Application (PSEA-T-CTA)/
Diffusion du Modèle d'évaluation de l'innocuité et de l'efficacité des protocoles—Demande d'essai clinique (MEIEP-DEC)
17 March 2009

Rick Doblin PhD
President
Multidisciplinary Association for
Pschedelic Studies
3 Francis Street,
BELMONT, Massachusetts
USA 02478-2218
(617) 484-8711

No Objection Letter RE: Protocol # MP-4

Dear Dr. Doblin:

I am pleased to inform you that the information and material to support your Clinical Trial Application for MDMA, control number 127822, received on February 16, 2009, have been reviewed and we have no objection to your proposed study.

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 for drugs marketed in Canada and in clinical trials, any serious and unexpected adverse drug reaction occurring inside or outside Canada should be reported to both MHPD and TPD until completion of the trial then the reports should be send to MHPD only.

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

Yours sincerely,

[Signature]

Elizabeth Komsta, M.Sc, Ph.D.
A/Manager - Clinical Trials Group II
Office of Clinical Trials

EK/en Canada