



Health
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Santé
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Healthy Environments
and Consumer Safety
Branch

Direction générale,
Santé environnementale et
sécurité des consommateurs

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Your file Votre référence

November 4, 2011

Our file Notre référence

11-121010-259
9630-M2435

Dr. Gabor Maté
941 22nd Ave W
Vancouver BC V5Z 2A2

Dear Dr. Maté:

The Office of Controlled Substances (OCS) has received information that you may be conducting a clinical trial using ayahuasca to treat addiction in Canada without first having received the proper authorization from the OCS or the Therapeutics Products Directorate (TPD).

Ayahuasca contains three substances listed in Schedule III to the *Controlled Drugs and Substances Act* (CDSA): N, N-dimethyltryptamine (DMT), harmaline and harmalol. As such, ayahuasca is considered to be a controlled substance by virtue of Section 2(2) of the CDSA which states that anything that contains a controlled substance is also a controlled substance.

Except as authorized under its related regulations, activities, i.e. possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production of controlled substances is prohibited under the CDSA.

In accordance with section J.01.003 of Part J of the *Food and Drug Regulations* (FDR), no person other than a licensed dealer may **produce, make assemble, import, export, sell, provide, transport, send or deliver** a restricted drug, or possess it for the purpose of such activities, unless otherwise authorized under these Regulations.

Clinical trials of drugs in humans are regulated in Canada under Part C, Division 5 of the FDR. A clinical trial is an investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.

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