

- 2 -

Before conducting clinical trials with a controlled substance, two key steps must be taken. The study sponsor must submit a Clinical Trial Application to Health Canada. Provided that Health Canada has no objection to the study proceeding, in the case of a clinical trial involving a controlled substance, the researcher then needs to apply for an exemption under Section 56 of the CDSA from the OCS. If an exemption is granted, an authorization letter is forwarded to the supplier to provide the substance to the researcher. The conduct of the clinical trial will be subject to the applicable requirements under Division 5, including record keeping, drug accountability, adverse event reporting, and good clinical practices.

Please note that performing regulated activities with controlled substances without a valid licence or an authorization, is an indictable offence under the CDSA. You are required to immediately suspend all regulated activities.

If you do not immediately cease all regulated activities with controlled substances, we will contact, within 30 days of the date of this letter, the Royal Canadian Mounted Police for enforcement action as they deem necessary.

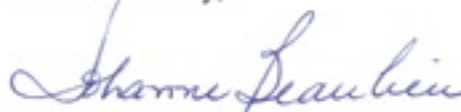
Please submit a written statement indicating that you are not and will not conduct any regulated activities with ayahuasca without a valid exemption. The original copy of a written response, signed by you must be received in this Office by November 22, 2011.

To obtain a copy of the *Controlled Drugs and Substances Act* and its Regulations, please visit the Justice Canada's website at:  
<http://laws.justice.gc.ca/en/C-38.8/index.html>

If you have any questions regarding clinical trials, please contact the Office of Clinical Trials at (613) 941-2132 or by email at [OCT\\_BEC\\_Enquiries@hc-sc.gc.ca](mailto:OCT_BEC_Enquiries@hc-sc.gc.ca)

If you have any questions regarding section 56 exemptions for the use of controlled substances in a clinical trial, please contact Ms. Kim Barber at 613-941-2130 or by email at [exemption@hc-sc.gc.ca](mailto:exemption@hc-sc.gc.ca).

Yours sincerely,



Johanne Beaulieu  
Director  
Office of Controlled Substances

c.c. Mark Kozlowski, National Compliance and Exemption Division, OCS.  
Candice Hilder, Good Clinical Practices Unit, Inspectorate, HPFB.  
Dr John Patrick Stewart, Office of Clinical Trials, HPFB.