

Minister of Health



Ministre de la Santé

Ottawa, Canada K1A 0K9

Jessica Rochester, Ph.D.
President
Céu do Montréal
5706 Queen Mary Road
Hampstead Quebec H3X 1X6

OCT 23 2012

Dear Dr. Rochester:

I am writing further to your request to be authorized to import, possess and transport a preparation containing N, N-dimethyltryptamine (DMT), harmalol, and harmaline.

Your request is made pursuant to Section 56 of the *Controlled Drugs and Substances Act* (CDSA) which gives me the discretionary authority to exempt a person or a class of persons from the application of all or any of the provisions of the Act or its regulations. Section 56 refers specifically to my ability to grant exemptions for medical and scientific purposes, and exemptions have been granted for such purposes. The section also allows me to grant exemptions that are otherwise in the public interest, and exemptions have been granted almost exclusively for law enforcement purposes.

I have considered all of the material and information provided, including Mr. Ruby's letters of June 11, 2012, and June 28, 2012. In forming my opinion as to whether granting the requested CDSA exemption is in the public interest, I have considered the purposes of the CDSA which are the protection of public health and the maintenance of public safety; the Government's associated National Anti-Drug Strategy; the scientific evidence on the harms associated with use of the controlled substances in question; your suggested risk minimization measures; the form in which you propose to use the substances; and the specific purposes for which you have sought an exemption.

The CDSA objectives of protecting public health and maintaining public safety are exemplified by the Government of Canada's National Anti-Drug Strategy. The Strategy was launched in 2007 as the federal government's comprehensive response to fighting illicit drug use in Canada. The goal of the Strategy is to contribute to safer and healthier communities by reducing and contributing to the elimination of illicit drug use in Canada. The Strategy includes three action plans: preventing illicit drug use, treating people with illicit drug dependencies, and combatting the production and distribution of illicit drugs.

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As you know, DMT, harmalol, and harmaline are controlled substances under Schedule III to the CDSA. In addition, these substances are listed in the Schedule to Part J of the *Food and Drug Regulations* (FDR) which govern substances that have no recognized medical use. Part J of the FDR authorizes the use of these substances in drug analysis test kits or by an institution for clinical use or laboratory research. DMT is also included in the Schedule to the United Nations 1971 Convention on Psychotropic Substances, to which Canada is a signatory, an objective of which is to prevent and combat abuse of listed substances and the illicit traffic to which it gives rise.

These three substances were scheduled under the CDSA because of concerns about their potential health and safety risks. DMT is known to induce psychotropic and hallucinogenic effects when consumed. These effects are caused by DMT-induced changes in the way the brain processes information, resulting in perceptual changes or distortions and hallucinations. Typically, DMT is degraded by the enzyme monoamine oxidase (MAO); however, harmala alkaloids are known to inhibit MAO.

Clinical studies in humans have shown that administration of DMT is associated with increases in blood pressure, heart rate, and pupillary diameter as well as nausea/vomiting, increased deep tendon reflexes and changes in some neuroendocrine system parameters. Some of these effects may pose risks to the health of individuals, especially those who may be suffering from known or underlying physical disorders. For example, someone suffering from cardiovascular disease could be at an increased risk of experiencing adverse health effects from consuming DMT since DMT places a stress on the cardiovascular system. Psychological harm may come to those who have an existing psychological disorder such as schizophrenia, or those having a predisposition to such a disorder, since hallucinogens have been shown to precipitate transient or prolonged psychotic episodes or to exacerbate existing psychiatric disease.

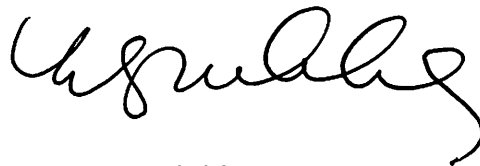
In addition to the health and safety risks associated with the use of DMT, the consumption of harmala alkaloids, such as harmaline, can result in serious and potentially fatal food and drug interactions due to the MAO inhibitor effect of these substances. The ingestion of certain foods or drugs, such as selective serotonin reuptake inhibitors, along with MAO inhibitors such as harmala alkaloids may result in serotonin syndrome, which is characterized by excessive levels of the neurotransmitter serotonin, and can be fatal.

The concentrations of the controlled substances DMT and harmala alkaloids such as harmaline found in the preparation you propose to use vary depending on the plant specimens collected, the region from which the plant specimens were harvested, variations in climate and, for DMT, the time of day of harvest. The method used to make the preparation may also affect the concentration of these controlled substances. Furthermore, the effects associated with the use of the preparation will depend on how much of it is consumed, the way in which it is consumed, and whether or not other substances, drugs or foods are also consumed. Scientific information, though limited, indicates that specific preparations of these plants with known amounts of these substances can produce effects similar to those resulting from the use of the individual substances, including nausea/vomiting, psychoactive effects, effects on the cardiovascular system, pupillary dilation, and changes in hormone levels and in immune system parameters. The potential for harms to human health is affected by the variation in concentration of the active substances and how much is consumed.

Given the known adverse effects and potential harms to human health associated with use of these substances and their potential diversion to the illicit market, such an exemption would not be in keeping with the purposes of the CDSA. After careful consideration, I have determined that a section 56 exemption authorizing the importation, possession and transportation of DMT, harmalol and harmaline would not be in the public interest.

Thank you for writing.

Sincerely,

A handwritten signature in black ink, appearing to read 'Leona Aglukkaq', written in a cursive style.

Leona Aglukkaq
Minister of Health