Health Canada
Santé Canada

Address Locator 0300B
Ottawa ON K1A 0K9

2020-07-09

HC6-53-37-7
HC6-70-92-8

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Authorization 50593.07.20
Expiry Date: 2021-07-02

"Analysis of Psilocin and Psilocybin Extracts and Analogs"

Wilfred A. Jefferies:

This letter amends and replaces the authorization letter dated July 2, 2020, in order to change the authorization from 50494.06.20 to 50593.07.20. In response to the application submitted by the University of British Columbia to Health Canada to use a restricted drug for scientific purposes, the following authorization is being granted to you pursuant to section J.01.059 of Part J of the Food and Drug Regulations (FDR).

With respect to the restricted drug listed below, and in accordance with the protocol specified above, you are hereby authorized to carry out laboratory research with the restricted drug at the institution listed in your research protocol, and to possess the restricted drug for the purposes of such research.

The authorization herein is only applicable if you comply with all applicable requirements of Part J of the FDR and the following qualifications and limitations:

(1) You may only possess the controlled drug listed below, up to the quantity indicated:

Substance Name	Maximum Quantity
Psilocybin	50 mg

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(2) You may only possess the restricted drug listed above if your possession is for the purpose of and in connection with research at the University of British Columbia.

(3) You may only possess the restricted drug listed above if it is obtained from the supplier below. On the basis of the information supplied, an authorization to sell the restricted drug listed above to the University of British Columbia is being issued to the supplier (copy attached);

Supplier

Toronto Research Chemicals Inc.
2 Brisbane Rd
North York ON M3J 2J8

(4) You may only be in possession of the restricted drug listed above if such possession is for the following purpose:

Note: purpose must be marked with an "X" to be applicable.

[X] to use *in vitro* in accordance with the research protocol submitted;

[ ] to administer to animals in accordance with the research protocol submitted.

(5) The restricted drug must be used solely for the purpose marked above.

(6) You are required to maintain records with respect to your possession and use of the restricted drug in accordance with sections J.01.081, J.01.084, J.01.085, and J.01.086 of Part J of the FDR. Pursuant to section J.01.080, you must record such information in a manner that permits an audit of the information to be made at any time. Specifically, you must keep and retain for a period of two years from the making of such record, the following information:

- the name, date and quantity of any restricted drug purchased or received;
- the name and address of the person from whom the restricted drug was received;
- the names and qualifications of every person who makes use of the restricted drug; and
- full clinical data with respect to the use of the restricted drug.

You shall make such records available to the Minister or an inspector upon request.

(7) You must safeguard the restricted drug from theft in a satisfactory manner and report any theft or loss within 72 hours of its discovery to the Compliance and Monitoring Division, Office of Controlled Substances, by emailing: hc.ocs.reporting-rapporter.bsc.sc@canada.ca.

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(8) Colleagues, assistants, technicians, etc. participating in the same project, who are under your direction and control, are also authorized to the same extent and for the same purpose as you are. You are responsible for any portion of the restricted drug listed above that is used by such an individual.

(9) If the research project is terminated before the expiry of this authorization, you must notify the Office of Controlled Substances of the remaining inventory of the restricted drug kept under this authorization.

(10) You must inform the Office of Controlled Substances if you leave the project before it is completed or terminated, so that a formal transfer of responsibilities for the controlled drug to another researcher may be provided.

(11) You must obtain prior authorization from the Office of Controlled Substances before using any restricted drug remaining from this project within the context of another research project, whether that research project is your own or that of another researcher.

(12) You are responsible for the destruction of any unused or expired restricted drugs. The destruction of a restricted drug must be witnessed by one of your research colleagues that works under your supervision or direction and on the same project listed on this exemption. Immediately following the destruction, you and the witness are required to sign and date a joint declaration attesting that the restricted drug was completely destroyed, to which each signatory must add their name in printed letters. You are required to keep and retain for a period of two years from the date of the making of the record:

- the municipal address of the place of destruction;
- the specified name of the restricted drug to be destroyed and, if applicable, the brand name of the product containing it or the name of the compound containing it;
- the form and quantity of the restricted drug to be destroyed or the product or compound containing it and, if applicable, its strength per unit, the number of units per package and the number of packages;
- the method of destruction;
- the date of the destruction; and
- the joint declaration signed by you and the witness.

You shall make such records available to the Minister or an inspector upon request.

(13) You will permit entry by any inspector designated under the CDSA, at any reasonable time to ensure compliance with the exemption and in accordance with sections 31 and 32 of the CDSA.

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This exemption expires on the earliest of the following dates:

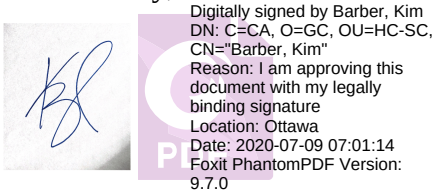
- the date you leave the research project;
- the date the research project is completed or terminated;
- the date the quantity of restricted drug authorized by this authorization has been entirely used;
- the date on which this authorization is replaced by another authorization;
- July 2, 2021.

If you plan to continue working on the same research project beyond the expiry date of this authorization, and you have any restricted drug remaining in your inventory, the institution must request on your behalf, an extension or a new authorization before the expiry date of this authorization.

Failure to comply with the terms and conditions of this exemption may, among other things, result in immediate suspension of this exemption, and ultimately, in its revocation.

If you have any further questions regarding this exemption, please do not hesitate to contact the Exemptions Section at hc.exemption.sc@canada.ca.

Yours sincerely,



Kim Barber
Associate Manager
Authorizations Division
Office of Controlled Substances

Attachment