

Therapeutic Products Directorate
11 Holland Ave
Address Locator: 3002A
Ottawa, ON K1A 0K9

30 August 2017

Application No. 271803

Olivia Sobczyk
Lab Manager
Thornhill Research Inc.
210 Dundas St. W., Suite 200
Toronto ON M5G 2E8
Canada

Re: Investigational Testing Application - Class II, Screening Deficiency Letter

Dear Olivia Sobczyk:

This is in reference to your Application for an Investigational Testing Authorization for the Ra-Mr System received on 22 August 2017 and submitted pursuant to Part 3 of the *Medical Devices Regulations*.

Pursuant to the requirements of Part 3 of the *Medical Devices Regulations*, the following information is considered to be deficient and is required before your application can be accepted for review:

1. The duration of the study in the protocol provided states that recruitment will take place between October 2016 and January 2017; additionally it is stated that study procedures will be conducted between May 2016 and January 2017. Confirm the time frame for the study, i.e., the duration of the enrolment phase, the duration of the treatment phase, and the duration of the follow-up phase. Also include the approximate duration from the start of enrolment to the end of the follow-up appointments.

In accordance with the Therapeutic Products Directorate policy entitled *Management of Applications for Medical Device Licences and Investigational Testing Authorizations* dated April 6, 2001, failure to provide a complete response to this request within fifteen (15) days will result in the issuance of a rejection letter. Please provide your written response to:

Information Dissemination Unit
Licensing Services Division
Medical Devices Bureau
11 Holland Ave
Ottawa, ON K1A 0K9
Address Locator: 3002A

NOTE: Your response may be submitted by e-mail to device_licensing@hc-sc.gc.ca, or sent by mail to the address above on a CD or DVD if it is too large to be sent by e-mail. Please refer to the following notice for the required format: <http://web.hc-sc.gc.ca/dhp-mpps/prodpharma/activit/announce-annonce/ita-notice-nonectd-aee-avis-eng.php>

If you have any questions regarding your application, please contact Bisi Lawuyi, Manager, Investigational Testing & Special Access Division, at 1-613-946-6554, or by e-mail at: Investigational_Testing@hc-sc.gc.ca.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Bisi Lawuyi'.

Bisi Lawuyi
Manager
Investigational Testing & Special Access Division
Medical Devices Bureau

BL/jfl