Health Canada Santé Canada

Regulatory Operations and Enforcement Branch
Medical Devices Inspections – Central
201 - 370 Speedvale Road West
Guelph, ON N1H 7M7

Sent By Email

September 13, 2019

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Glia Inc.
54 Craig Street
London, ON N6C 1E8
Company's email: tarek@tarek.org

Attention: Mr. Tarek Loubani, Owner

SUBJECT: NOTICE OF INSPECTION

Following our telephone and email communication yesterday, this letter confirms that your establishment has been selected for a regulatory inspection. This inspection will be carried out as part of Health Canada's Medical Devices Inspection Program. It will assess your establishment's compliance with the *Food And Drugs Act* and Canada's Medical Devices Regulations.

The inspection is scheduled for October 24, 2019, beginning at 10 am. I estimate it will take 2 days, though the time will depend on the amount of information to review.

To prepare for the inspection, please read our *Guidance Document on the Medical Devices Inspection Programme* (GUI-0064). You can find it on our website at www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/md_insp_prog-prog_insp_mm-eng.php.

Please also provide the following information by October 15, 2019, as applicable:

- a copy of the Medical Device Establishment Licence Application Form (FRM-0292) for the current year
- a list of manufacturers for the medical devices your establishment imports
- a list of manufacturers for the medical devices your establishment distributes (i.e. those

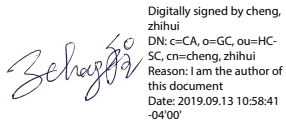
Canada

you get from a domestic manufacturer or importer and further distribute)

- a list of medical devices offered for sale in Canada by your establishment, along with their class of risk
- a list of medical devices for which your establishment is the legal manufacturer (i.e. you sell the medical device under your own name or under a trademark, design or name owned or controlled by your establishment)
- copies of the procedures attested to in the FRM-0292 for the current year, including:
    - maintenance of distribution records
    - complaint handling
    - recalls
    - mandatory problem reporting
    - handling, storage, delivery, installation, corrective action and servicing

Feel free to contact me if you have any questions or require additional information about your inspection.

Sincerely,



Larry Cheng, Inspector
Medical Devices Inspections – Central

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