Health Canada Santé Canada

NATURAL AND NON-PRESCRIPTION HEALTH PRODUCTS DIRECTORATE

FSRN NOTICE OF ACCEPTANCE

TO: Mr. Clyde Granger	**FROM:** Mr. Thilina Dewpura
COMPANY NAME: Gemini Pharmaceuticals Inc.	**DATE:** January 16, 2019.
RECEIVER'S FAX NUMBER:	**PAGE(S): 2**
RECEIVER'S TELEPHONE NUMBER:	**SENDER'S CONTACT NUMBER:** Tel: 613-355-3862
APPLICATION TYPE: FSRN Renewal	**COMPANY CODE:** 16007
FILE NO.: 206957	**SUBMISSION NO.:** 242404

Re: Notice of Acceptance for Foreign Site Reference Number 5000275
Gemini Pharmaceuticals Inc.
87 Modular Avenue, Commack, New York, 11725, USA.

Dear Mr. Granger**,**

The Natural and Non-prescription Health Products Directorate (NNHPD) is pleased to inform you that the Good Manufacturing Practice (GMP) information submitted for the above Foreign Site Reference Number (FSRN) Application has been assessed and deemed adequate. Your reference number is **5000275** and is valid until **10 May 2021** for the following activities: manufacturer, packager, labeler.

Following the assessment of this submission, there were no observations noted.

It is important to note that the issuance of a FSRN is not an authorization for direct export of Natural Health Products (NHPs) into Canada, nor is it considered equivalent to a site licence. The issuance of a FSRN is not an exercise of a statutory power of decision under the Natural Health Product Regulations (the Regulations) as foreign manufacturers are not subject to Canadian regulations. Instead, the FSRN process is a service offered by Health Canada to permit Canadian importers to more efficiently demonstrate compliance with section 43(2) of the Regulations (http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/). It also relieves foreign sites from having to repeatedly provide the same GMP information to multiple importers.

With respect to the import for sale of products, it is, pursuant to s. 43(2) and s. 100 of the Regulations, the responsibility of Canadian importers to demonstrate that products were manufactured, packaged, and labelled in accordance with requirements that are equivalent to those set out in the Regulations.

Please note, should Health Canada become aware of issues at a foreign site, the NNHPD will contact the relevant regulated parties (i.e. importers) in Canada to seek information to determine whether imported products comply with the Regulations.

Once a FSRN holder engages in a partnership with a licensed Canadian importer in order to export natural health products into Canada, the FSRN holder may authorize importers in Canada to access their information to support the importer's site licence application. Your authorization is to be given by completing the Foreign Site Reference Number Authorization Form found on the NNHPD website (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form_fsrn-nrse-eng.php). A separate authorization form must be provided to each importer as the information captured in the form will be specific to the business arrangement between the two companies. The regulated party (importer) is then responsible for providing the completed form to the NNHPD as part of their application for a site licence.

In order to maintain the status of your FSRN, it is necessary that you update your GMP information by filing an application for FSRN renewal before the date of expiry mentioned above. If you have any questions regarding the application process or if you need information on how to maintain your reference number, please contact the NNHPD by email at: NNHPD_DPSNSO@hc-sc.gc.ca.

Should you have any questions concerning this notice, please contact the Site Assessment Officer at the coordinates indicated at the top of this notice. Please note that the company code, file number, submission number, and foreign site reference number must be quoted on all correspondence regarding this submission.

Yours sincerely,

Shawn Lawless, A/Manager
Submission Management Division
Natural and Non-prescription Health Products Directorate