



NATURAL AND NON-PRESCRIPTION HEALTH PRODUCTS
DIRECTORATE

FSRN NOTICE OF ACCEPTANCE

TO: Dinesh Aavishkar	FROM: Brad Byrne
COMPANY NAME: Aavishkar Oral Strips Pvt. Ltd.	DATE: October 2, 2022
RECEIVER'S FAX NUMBER:	PAGE(S): 2
RECEIVER'S TELEPHONE NUMBER:	SENDER'S CONTACT NUMBER: Tel:
APPLICATION TYPE: FSRN Issuance	COMPANY CODE: 47801
FILE NO.: 251014	SUBMISSION NO.: 251014

**Re: Notice of Acceptance for Foreign Site Reference Number 5000577
Aavishkar Oral Strips Pvt. Ltd.
109/3, IDA, Phase-2, Sector-2, Lane 6, Cherlapally, Ranga Reddy (Dist.),
Hyderabad, Telangana, 500051, India**

Dear Mr. Dinesh Aavishkar,

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 **5000577** and is valid until **1 October 2023** for the following activities:

Activities	Authorized Activities	Specific Authorization	
		Sterile Dosage Form	Homeopathic Medicine
Manufacturing	YES	NO	NO
Packaging	YES	NO	NO
Labelling	YES	NO	NO

The following exception applies to your FSRN:

Your site has been found compliant with regards to the Good Manufacturing Practices (GMP) and deemed eligible to be pre-cleared. However, if an importer in Canada wishes to utilize your services, they must supply the **finished product test results, and stability records** pertaining to products handled by your site, as part of their site licence application in accordance with section 44 and 52 of the NHPR. It is your responsibility to ensure that this information is communicated to the importer prior to engaging in a business relationship.

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.

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, contact the NNHPD by email at: hc.nnhpd-dpsnso.sc@canada.ca.

Should you have any questions concerning this notice, contact the Site Assessment Officer at the coordinates indicated at the top of this notice. 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,



Heather Gilmer, Manager
Site Licence Assessment Unit
Natural and Non-prescription Health Products Directorate