

Bulletin to Temporary COVID-19 Site Licence Holders: End of the interim COVID-19 Site Licences

Background:

In March 2020, the Natural and Non-Prescription Health Products Directorate (NNHPD) of Health Canada introduced interim measures to enable expedited site licensing for alcohol-based hand sanitizers to address shortages of these products on the Canadian market and meet public health recommendations due to the COVID-19 pandemic. On August 4, 2020, the NNHPD issued its first bulletin to COVID-19 site licence (SL) holders, “Bulletin to Temporary COVID-19 Site Licence Holders: What to expect at the end of the public health emergency”, which committed to providing 60 days notice in advance of the end of the interim measures for site licensing. In December 2020, NNHPD launched a survey to all temporary COVID-19 SL holders, which informed the transition plan, as did the current demand for hand sanitizers.

Overview of Transition:

The present bulletin is intended to provide information to persons who received an interim COVID-19 SL (as denoted by the prefix “COV#####”) for manufacturing, packaging, labelling and/or importing alcohol-based hand sanitizers, which are considered natural health products (NHPs) under the *Natural Health Products Regulations* (NHPR).

Specifically, this bulletin is to provide temporary COVID-19 SL holders with 60-days notice of the end of the temporary COVID-19 site licenses on September 30, 2021. Persons who wish to maintain the ability to manufacture, package, label and/or import alcohol-based hand sanitizers are being provided, through this bulletin, with a pathway to obtain a site licence in accordance with Section 28 of the NHPR.

Persons who do not apply for a site licence by September 30, 2021 at 11:59pm PST must stop manufacturing, packaging, labelling and/or importing their alcohol-based hand sanitizers by that date. At any point during the application process, should the application be refused, the manufacturing, packaging, labelling and/or importing of alcohol-based hand sanitizers must stop as of the date of the notice of refusal. Health Canada may undertake compliance and enforcement actions as required to prevent and /or address risks to the health of Canadians.

Temporary COVID-19 SL holders may continue activities under their temporary COVID-19 SL until a decision is issued on their SL application, so long as the application was submitted complete and on time. The service standards normally associated with new site licence applications will not apply to the COVID-19 transition. However, the NNHPD will strive to issue an acknowledgement of receipt within 30 days of receiving an application. The total transition time, including the time to review an application, will depend on the total volume of applications received and the level of completeness of each application.

As of the date of this bulletin, the NNHPD will no longer accept amendments to interim COVID-19 SLs.

At a Glance: COVID-19 SL transition

- All COVID-19 SL holders who want to continue their activities must follow the transition pathway outlined herein.
- You are required to submit a complete application for a site licence no later than **September 30, 2021** at 11:59pm PST.
- The service standards normally in place for new applications will not apply to the COVID-19 SL transition.
- You will receive an **Acknowledgment of Receipt** within 30 days of filing.
- You may continue activities under the COVID-19 SL until a decision is issued.

Next Steps:

COVID-19 SL holders may elect one of the following course of actions, as appropriate.

1- If you have already stopped or never carried out activities under your interim COVID-19 site licence

- Discontinue your interim COVID-19 site licence (SL). To do so, send us an email at hc.nnhpd-dpsnso.sc@canada.ca to request that your interim COVID-19 SL be discontinued ahead of the September 30, 2021 end date. Your email needs to include a cover letter, reference your COVID-19 SL number (as denoted by the prefix "COV####") and the discontinuation date.
- NNHPD will confirm via email that your request was received.
- If you take no action, the activities listed on your interim COVID-19 SL will no longer be allowed after September 30, 2021.

2- If you do not want to continue activities beyond September 30, 2021

- Discontinue your interim COVID-19 SL by following the steps described above, as required.
- If you take no action, the activities listed on your interim COVID-19 SL will no longer be allowed after September 30, 2021.
- After September 30, 2021, you may **liquidate the remaining alcohol-based hand sanitizer stock** that was imported or manufactured while the interim COVID-19 SL was valid. You may not continue to manufacture and/or import new products after this date. You will be asked to confirm that you have ceased these activities.
- You must retain samples of your product(s) and records to enable a recall, if needed, as per sections 53-58 and 62 of the NHPR.

3- If you want to continue activities beyond September 30, 2021

- Submit a complete site licence application (SLA), as per Section 28 of the NHPR, by September 30, 2021 at 11:59 pm PST.
- To do so, refer to the following Appendices:
 - Appendix 1: Interim COVID-19 SL transition process;
 - Appendix 2: Good Manufacturing Practices (GMP) related application requirements; and
 - Appendix 3: SLA refusal criteria.
- Incomplete or non-compliant applications will be refused and activities will need to cease as of the date of the refusal notice.
- Persons who do not submit on time will not be permitted to continue operations beyond September 30, 2021, as the activities listed on your interim COVID-19 SL will no longer be allowed after this date.

Did you already submit a SLA before receiving this bulletin?

- ✓ Review the information provided in this bulletin;
- ✓ Withdraw your previous application if it does not meet the requirements outlined herein; and
- ✓ Submit a new application through the COVID-19 SL transition pathway.

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