

Appendix 3: COVID-19 SLA refusal criteria

Failure to meet the requirements of the NHPR, including Section 28 of the NHPR (application requirements) and Part 3 of the NHPR (NHP GMPs) will result in a refusal. In the case of significant deficiencies, as outlined below, NNHPD will not be issuing an Information Request Notice (IRN) prior to a refusal.

1. Incomplete application

- Incomplete or incorrect Web SLA application form,
- Missing contact information or Designated Party Authorization (DPA) form (if required),
- Wrong company code or COVID-19 SL number listed or not provided,
- GMP evidence not provided,
- Application contains damaged/corrupted files

If an application is refused for the reasons listed above and is resubmitted, with the correction(s) made, by September 30, 2021, the application will be accepted.

2. Non-compliance with Part 3 of the NHPR (NHP GMPs)

- Incomplete GMP evidence, records or SOPs,
- Critical risk 1 GMP deficiencies identified (refer to appendix 5 of the Good Manufacturing Practices Guidance Document for a complete listing of risk 1 deficiencies),
- Use of unacceptable raw ingredients with health risk issues (e.g. methanol),
- Evidence of importation or manufacture of unlicensed products,
- SOPs that do not meet the expectation outlined in appendix 4 of the Good Manufacturing Practices Guidance Document.

3. Incomplete or no response to an Information Request Notice (IRN)

Other deficiencies, beyond those listed above, may require additional information or clarification from the applicant, per Section 37 of the NHPR, which will be requested through an IRN. To ensure the efficiency of the regulatory review process, NNHPD aims to issue one complete IRN that includes application deficiencies that are not deemed significant. The applicant is responsible for providing a complete response, meaning a response that addresses each of the deficiencies listed. Incomplete IRN responses will result in a refusal.

The NNHPD will offer a longer timeline than usual (i.e., 30 days) for applicants to respond to an IRN, unless potential risks to health are identified. The NNHPD will not consider or grant requests for an extension as the information in support of GMP compliance ought to be readily available to the applicant to demonstrate its compliance with the NHP GMPs. Failure to respond to an IRN within the allotted time will result in a refusal.