

Natural and Non-prescription Health Products Directorate (NNHPD) Updates

Performance Standards for NHP Applications
September 21, 2022



Outline:

- NHP workload update: Product and Site licence applications
- Recent systems update

Workload update: Product and Site licence applications

Non-COVID Submissions Summary (April 1, 2021 to August 31, 2022)

Product Licence Submissions:

- Licensed **3,935** NHPs
54% Class I; 14% Class II; 33% Class III
- Refused 903 submissions

Site Licence Submissions:

- Licensed or renewed **718** Sites
- Refused **219** submissions

Client Service Inquiries:

- Received **5,936** inquiries
 - 96% of inquiries received a response



Non-COVID Product Licence Applications (April 1, 2021 to August 31, 2022)

- **Class I:** 95.7% year-to-date performance for new applications and amendments against the 60-day service standard
 - Total Refusal Rate: **17%**
 - Performance target for 2022-2023: **90%**
- **Class II:** 92.1% year-to-date performance for new applications and amendments against the 90-day service standard
 - Total Refusal Rate: **32%**
 - Performance target for 2022-2023: **90%**
- **Class III:** 64.9% year-to-date performance for new applications and amendments against the 210 day service standard
 - Total Refusal Rate: **17%**
 - Performance target for 2022-2023: unable to meet 90% until sustainable funding is obtained; Non-hypothetical applications prioritized based on date of receipt
- **Notifications:** Processed 60% of the notifications received in 2022
 - Performance target for 2022-2023: none; company updates prioritized



Market Authorization

- ✓ Issued Industry survey for licensed products (April 5 – May 15, 2022)
- ✓ Updated the Licensed Natural Health Products Database (LNHPD), which now reflects the market status of a product, as either “marketed” or “not marketed” – July 25, 2022
- ✓ Published the Natural Health Products Market Notification Web Form, enabling applicants to submit their market status, for licensed NHP products to the NNHPD, using the online form – July 25, 2022
 - Currently there is no service standard for updating the LNHPD to reflect when the information is received.



Non-Covid Site Licence Applications (April 1, 2022 to August 31, 2022)

- **Stream I:** 41% year to date performance for new applications and amendments
 - Total Refusal Rate: 28%
 - Performance target for 2022-2023: unable to meet 90% until sustainable funding is obtained
- **Stream II:** 50% year to date performance for new applications and amendments
 - Total Refusal Rate: 43%
 - Performance target for 2022-2023: unable to meet 90% until sustainable funding is obtained
- **Renewals:** completed 286 (**200 domestic**) renewals this fiscal year
 - Total Refusal Rate: 13%
 - Performance target for 2022-2023: clear the backlog of renewals, interim measures for FSRNs remain in effect until further notice
 - Applicants that fail to submit an application to renew at least 30 days before their site licence expires will NOT be prioritized
- **COVID SL transition:** 46 licensed and 185 refused/withdrawn
 - Performance target for 2022-2023: none, but will complete the transition



Applicant driven issues impacting licence renewal completions:

- Failure to submit an application to renew the site licence at least 30 days before the licence expiry
- Failure to submit an application to renew the site licence through the correct channel (e.g., applications submitted via old ePost conversations)
- Failure to submit all aspects of the application in one of the two official languages (EN or FR) and /or in a way that supports an efficient review
 - Failure to provide relevant documents/evidence in an organized and distinguishable manner (e.g., file names does not match the SOP; all documents saved under one file or in a PDF format; file names are not following the suggested naming convention, too many characters and/or file names containing foreign characters)
- Failure to respond to an information request notice (IRN) on time (e.g., multiple requests for extensions)
- Failure to submit a complete and compliant application to renew the site licence (i.e., GMP deficiencies prevent further assessment)
- Failure to submit ONLY an application to renew a site licence (i.e., requests for modification like to add a new foreign site must be submitted as a amendment)

Quality Updates Currently Underway



- ❑ Site Licencing Bulletins – **October, 2022**
 - SL Submission Format and Structure
 - SL Submission Refusal Criteria (extend refusal criteria for all site licence submissions -phase 2)

- ❑ Impacts of Inspections on Site Licensing – **Summer 2022**
 - Sites with a “Compliant” inspection rating could expect a lighter touch assessment during renewal, resulting in a more efficient renewal process

- ❑ Product FPS Updates - **Fall 2022**
 - Risk-based criteria for quality amendments; Revision of FPS form

- ❑ Guidance prioritization work {*Quality guide, GMP GD, SL GD*}

- ❑ Targeted updates to FPS User Guide - **Fall 2022**
 - Test parameters added; Changes to tolerance limits; Changes to an ingredient to which a test parameter applies

Systems Improvements to Support Priorities

Web SLA update on April 29th, 2022 (version 3.0) included the following changes:

- Added a validation service to the form
- Added the ability to capture notifiable changes
- Added new fields in response to finding from the CESD's audit of the NHP program
- Improved the form's design and user experience

Other Key Improvements:

- Enabled market status in the LNHPD (i.e. Applicants can inform us if products are marketed to help enable future cost recovery)
- Enabled validation of the Antioxidants and Aromatherapy monographs in the Web PLA



Q&A



Natural and Non-Prescription Health
Products Directorate (NNHPD)

Contact us directly at:

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Product Licence Submissions (Non-COVID):

Class III IRN Rate: 90%

Refusal Rate: 31%



Common deficiencies:

- For Class III applications we are still seeing a lot of refusals on minimum criteria; such as, links and abstracts being provided instead of full-text evidence.
- Failure to respond to all points on an IRN, comply with options provided or failure to correctly respond to the IRN
- Companies submit unsolicited changes that are not accepted as per section 6.2.2 of the NHP MAP resulting in refusal

REMINDERS:

- For Class II and III applications the web form **does not validate against monographs**. Applicants should ensure that pre-cleared information claims and risk information are supported by dosing information.
- Hypothetical products are currently **not being prioritized**. Applicants should ensure the web PLA is filled out correctly to avoid delays for non-hypothetical products.

Site Licence Submissions (Non-COVID):

Overall IRN Rate: 59%

Overall Refusal Rate: 35%



Common Deficiencies:

- Failure to submit an application to renew the site licence at least 30 days before the licence expiry
- Failure to submit all aspects of the application in a way that supports an efficient review (e.g., Documents are not in one of the two official languages (EN or FR); documents not organized or easily distinguishable)
- Companies provide records (e.g., stability and finished product testing) for products that are not intended for the Canadian market

REMINDER:

- Applications must be submitted electronically via ePost Connect using the Web SLA v3.0 form. Paper based or PDF versions are no longer accepted and will be refused.