

# Status of Applications Quarterly Report

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**Quarter 2**  
(July 1, 2009 to September 30, 2009)

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**Quarter 2 (July 1, 2009 to September 30, 2009)**

***Natural Health Products Directorate  
Health Canada***

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The *Status of Applications Quarterly Report* is a publication of Health Canada's Natural Health Products Directorate (NHPD), the federal department responsible for the regulation of natural health products sold in Canada. The purpose of this report is to provide the Canadian public with statistical data on the product and site licence applications received and processed by the NHPD.

**Reporting Schedule\*:**

- 1<sup>st</sup> Quarter: April 1 to June 30
- 2<sup>nd</sup> Quarter: July 1 to September 30
- 3<sup>rd</sup> Quarter: October 1 to December 31
- 4<sup>th</sup> Quarter: January 1 to March 31

\*Based on fiscal year, not calendar year.

**Questions, comments or feedback** regarding the content of the *Status of Applications Quarterly Report* may be addressed to **NHPD\_DPSN@hc-sc.gc.ca**.

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## Performance Summary and Highlights

Since the implementation of the *Natural Health Products Regulations* in January 2004 until the end of September 2009, Health Canada has received 41,872 Product Licence Applications (PLAs). Of this total, **30,464 PLAs have been completed, including the issuance of 15,790 Product Licences which represents 20,674 products.** The remaining completed applications were either refused by NHPD or withdrawn by the applicant. In total, 977 companies have received a product licence to date.

### Highlights

**15,790**

NHPs licensed  
since 2004

**30,464**

PLAs completed  
since 2004

The number of PLAs completed by NHPD per quarter has continued to rise during Quarter 2 (FY 09-010) to 4717, surpassing the 3520 from Quarter 1 (FY 09-10) by 34%. As of September 30, 2009, 839 applications remained in the administrative processing queue for issuance of licences and 221 applications for issuance of a refusal.

To date, 59% of applications in “backlog” and 67% of “regular workload” applications have been completed or are in the process of being completed. In addition, 82% of “backlog” applications and 77% of “regular workload” applications have been addressed (see Appendix A for definitions).

During this quarter, the reduction in the number of non-addressed backlog applications by 9.5% is largely as a result of the following:

- Process improvements implemented in the Non-Traditional application review stream
- Addition of administrative resources to minimize delays in communicating decisions to applicants.

While the priority is addressing backlog applications, NHPD continues to report improvement with regards to regular workload applications. Only 23% of applications received since April 1, 2008 have not yet been addressed, an improvement of 7% over the previous quarter which is largely a result of:

- The use of NHPD-developed pre-cleared information such as NHPD Labelling Standards and Monographs by applicants as a tool to expedite applications
- Process improvements implemented in order to expedite Transitional DIN & Compendial applications
- The implementation of the Initial Assessment process for incoming Non-Traditional submissions within a few months after receipt

## Quarter 2 (July 1, 2009 to September 30, 2009)

During this quarter, a total of 4717 PLAs were completed, 1540 of which were refused for the following reasons:

- 49% were refused when applicants did not respond to a request for further information.
- 42% failed to meet basic application requirements.
- 7% were refused when the applicant's response to a request for further information did not meet the requirements.
- 1% did not meet the definition of a NHP.
- 1% were refused when significant changes were made to the product itself in response to a request for further information (i.e. an "unsolicited change").

### Highlights

**2647**

NHPs licensed  
during Quarter 2

**1540**

PLAs refused  
during Quarter 2

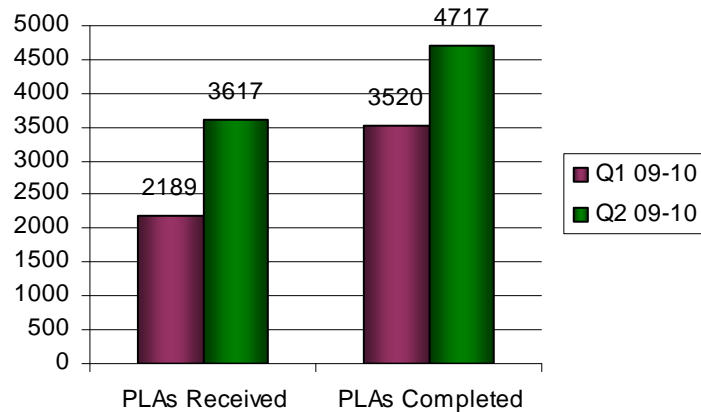
**530**

PLAs withdrawn  
during Quarter 2

## Quarter 2 Statistics (July 1, 2009 to September 30, 2009)

**Chart 1 – Total Number of Product Licence Applications (PLAs) Received and Completed during Quarter 2**

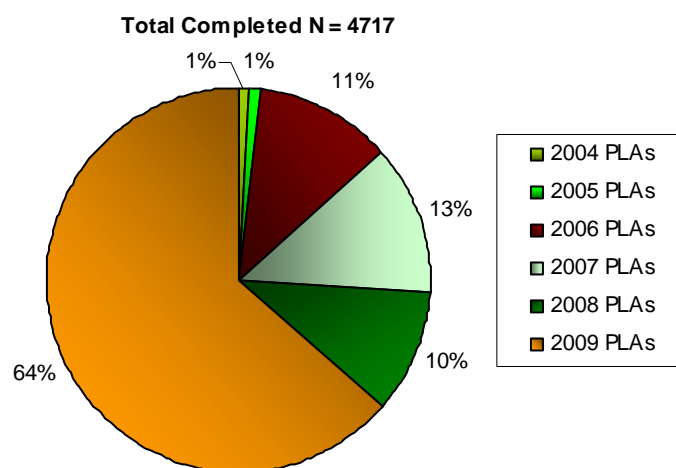
Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.



**Chart 2 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 2 (Licensed, Refused or Withdrawn)**

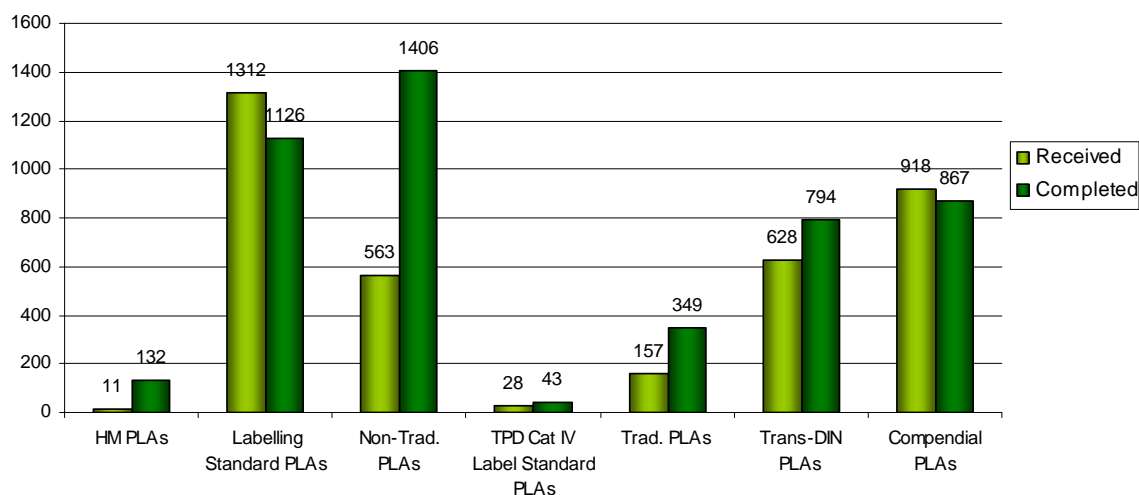


**Chart 3 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 2 (by Year of Application)**



**Chart 4 – Total Number of Product Licence Applications (PLAs) - by application type - Received and Completed during Quarter 2**

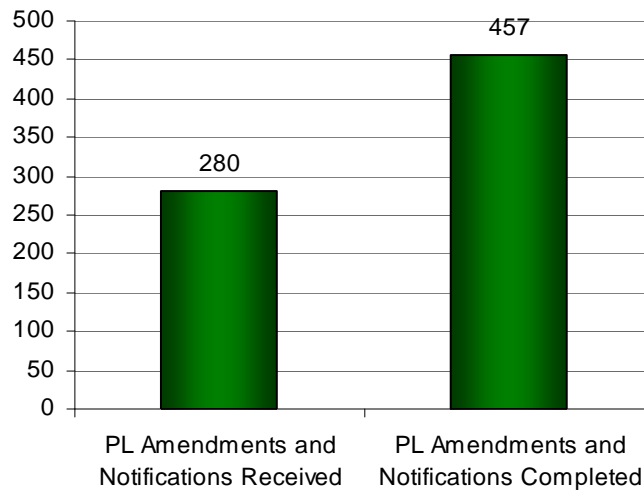
Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.



\* See Appendix A for definitions of acronyms found in Chart 4.

**Chart 5 – Total Number of Product Licence (PL) Amendments and Notifications Received and Completed during Quarter 2**

Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.



**Chart 6 – Total Number of Site Licence Applications (SLAs) Received and Completed during Quarter 2**

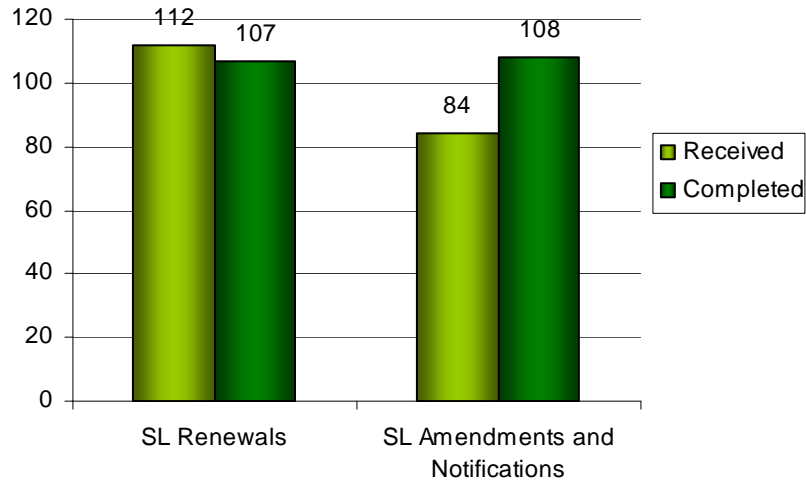
Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.





**Chart 7 – Total Number of Site Licence (SL) Amendments, Notifications and Renewals Received and Completed during Quarter 2**

Note – “Completed” includes all applications that were licensed, refused or withdrawn by the applicant.



## Update on the Product Licence Application *Backlog* and *Regular Workload*

As defined by the NHPD, the “backlog” consists of the 12,635 PLAs received before April 1, 2008 which were incomplete as of that date (i.e. the PLA was not licensed, withdrawn or refused). All other PLAs received on or after April 1, 2008 are considered regular workload and are not part of the PLA backlog the NHPD has committed itself to addressing by March 31, 2010. For the purposes of reporting, these are called “regular workload” PLAs.

As a result of the implementation of the Non-Traditional Process Improvement Project and other improvement initiatives, the number of incomplete “backlog” PLAs now equals 5131 PLAs, signalling a reduction of 59.4% from the original 12,635 PLAs.

### Highlights

**59%**

reduction of the backlog

**82%**

of backlog PLAs have been addressed

**Table 1: Total “Backlog” as of September 30, 2009**

Table 1 provides figures on the current status of the PLA “backlog”. Please note these numbers do not include amendments, notifications or applications relating to those natural health products in food formats that have yet to be classified as either foods or natural health products.

| Status   | Number      | Percentage of Total “Backlog” (12,635) |
|--|-------------|--|
| Licensed   | 2502        |  |
| In Licensing – administrative processing required                  | 44          |  |
| Refused  | 2763        |  |
| To Be Refused – administrative processing required                 | 110         |  |
| Withdrawn by applicant   | 2085        |  |
| <b>Addressed PLAs - Completed</b>                                  | <b>7507</b> | <b>59.4%</b>                           |
| Has received one or more Information Request Notice (IRN) or E-IRN | 2891        |  |
| <b>Addressed PLAs - Other</b>                                      | <b>2891</b> | <b>22.9%</b>                           |
| Require Initial Assessment to determine if file requires E-IRN     | 176         |  |
| To receive E-IRN   | 64          |  |
| Awaiting or undergoing full review                                 | 1063        |  |
| Halted pending internal decision related to safety or efficacy     | 937         |  |
| <b>Non-Addressed PLAs</b>  | <b>2240</b> | <b>17.7%</b>                           |

**Table 2: Total “Regular Workload” as of September 30, 2009**

Table 2 provides figures on the current status of all PLAs which were received on or after April 1, 2008 and are therefore not considered “backlog”. Please note these numbers do not include amendments, notifications or applications relating to those natural health products in food formats that have yet to be classified as either foods or natural health products.

| Status   | Number       | Percentage of Total “Regular workload” (15,727) |
|--|--------------|---|
| Licensed   | 7101         |   |
| In Licensing – administrative processing required                  | 795          |   |
| Refused  | 2140         |   |
| To Be Refused – administrative processing required                 | 109          |   |
| Withdrawn by applicant   | 366          |   |
| <b>Addressed PLAs – Completed</b>                                  | <b>10511</b> | <b>66.8%</b>                                    |
| Has received one or more Information Request Notice (IRN) or E-IRN | 1551         |   |
| <b>Addressed PLAs - Other</b>                                      | <b>1551</b>  | <b>9.9%</b>                                     |
| Applications (all types) recently received at NHPD                 | 537          |   |
| Require Initial Assessment to determine if file requires E-IRN     | 527          |   |
| To receive E-IRN   | 53           |   |
| Awaiting or undergoing full review                                 | 2050         |   |
| Halted pending internal decision related to safety or efficacy     | 483          |   |
| Miscellaneous Administrative Issues                                | 15           |   |
| <b>Non-Addressed PLAs</b>  | <b>3665</b>  | <b>23.3%</b>                                    |

## Appendix A – Acronyms and Definitions

|  |   |
|--|---|
| PL:  | Product Licence   |
| SL:  | Site Licence  |
| PLA:   | Product Licence Application   |
| SLA:   | Site Licence Application  |
| DIN:   | Drug Identification Number  |
| NHPD:  | Natural Health Products Directorate   |
| HM PLA:                                      | Homeopathic Medicines Product Licence Application   |
| Non-Trad. PLA:                               | Non-Traditional Product Licence Application   |
| Trad. PLA:                                   | Traditional Product Licence Application   |
| TPD Cat IV / Label Standard PLA:             | Product Licence Application citing a Category IV Monograph or Labelling Standard from the Therapeutic Products Directorate  |
| Trans-DIN PLA:                               | Transitional DIN Product Licence Application  |
| Compendial PLA:                              | Product Licence Application citing a monograph found in the NHPD's <i>Compendium of Monographs</i>  |
| Addressed:                                   | When NHPD issues a Product Licence, Notice of Refusal, Information Request Notice or when the applicant withdraws their application, the application is considered to be "addressed". |
| Backlog:                                     | All PLAs received before April 1, 2008 which were not complete as of that date  |
| Completed:                                   | When NHPD issues a Product Licence, Notice of Refusal or when the applicant withdraws their application, the application is considered to be "completed".                             |
| E-IRN:                                       | Information Request Notice focusing on critical evidence deficiencies   |
| Halted:                                      | An application which cannot be further processed due to the need for an internal decision related to safety and/or efficacy   |
| IRN:   | Information Request Notice  |
| Non-Traditional Process Improvement Project: | Project initiated by NHPD, in 2008, which involves screening Non-Traditional applications for critical evidence deficiencies through an initial assessment process                    |
| Regular workload:                            | All PLAs received on or after April 1, 2008   |