

Status of Applications Quarterly Report

Quarter 3
(October 1, 2009 to December 31, 2009)

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

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*:

- 1st Quarter: April 1 to June 30
- 2nd Quarter: July 1 to September 30
- 3rd Quarter: October 1 to December 31
- 4th 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**.

Table of Contents

Performance Summary and Highlights.....	- 4 -
Quarter 3 Statistics (October 1, 2009 to December 31, 2009)	- 6 -
Chart 1 – Total Number of Product Licence Applications (PLAs) Received and Completed during Quarter 3	- 6 -
Chart 2 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 3 (Licensed, Refused or Withdrawn).....	- 6 -
Chart 3 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 3 (by Year of Application).....	- 7 -
Chart 4 – Total Number of Product Licence Applications (PLAs) - by application type -Received and Completed during Quarter 3	- 7 -
Chart 5 – Total Number of Product Licence (PL) Amendments Received and Completed during Quarter 3	- 8 -
Chart 6 – Total Number of Product Licence (PL) Notifications Received and Completed during Quarter 3	- 8 -
Chart 7 – Total Number of Site Licence Applications (SLAs) Received and Completed during Quarter 3	- 9 -
Chart 8 – Total Number of Site Licence (SL) Amendments, Notifications and Renewals Received and Completed during Quarter 3	- 9 -
Update on the Product Licence Application Backlog and Regular Workload	- 10 -
Table 1: Total “Backlog” PLAs as of December 31, 2009	- 10 -
Table 2: Total “Regular Workload” PLAs as of December 31, 2009	- 11 -
Update on Amendments and Notifications	- 12 -
Table 3: Total “Regular Workload” Amendments as of December 31, 2009.....	- 12 -
Appendix A – Acronyms and Definitions	- 13 -

Performance Summary and Highlights

Since the implementation of the *Natural Health Products Regulations* in January 2004 until the end of December 2009, Health Canada has received 44,773 Product Licence Applications (PLAs). Of this total, **34,083 (76%) PLAs have been completed, including the issuance of 18,105 Product Licences which represents 23,560 products.** The remaining completed applications were either refused by NHPD or withdrawn by the applicant. In total, 1064 companies have received a product licence to date.

Highlights

18,105

NHPs licensed
since 2004

34,083

PLAs completed
since 2004

To date, 68% of applications in “backlog” and 67% of “regular workload” applications have been completed or are in the process of being completed. In addition, 94% of “backlog” applications and 78% of “regular workload” applications have been addressed (see Appendix A for definitions). Please note that as a result of the recent decision to have NHPs in a food format assessed by NHPD, the total number of backlog applications has risen to 12,976 from 12,635 as 341 NHPs in food format were received prior to April 1, 2008 and are now considered part of “backlog”. These applications are categorized as Non-Traditional and are now counted in all of NHPD’s application statistics. More information about these types of products can be found on NHPD’s website: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php>

During this quarter, the reduction in the number of non-addressed backlog applications by 66% from last quarter is largely as a result of the following:

- Traditional Process Improvement Project
- Publication of pre-cleared information such as: Soybean and Cod Liver Oil Monographs and 14 new Abbreviated Labelling Standards (AbLS)
- Process improvements implemented in the Non-Traditional application review stream including maximizing the use of previous NHPD decisions regarding acceptable claims and safety of ingredients
- Decisions made to proceed on previously halted applications including NHPs in food format, chromium and zinc picolinate and soybean extracts and isolates.

While the priority is addressing backlog applications, NHPD continues to report improvement with regards to regular workload applications. Only 22% of applications received since April 1, 2008 have not yet been addressed, largely as a result of:

- The use of NHPD-developed pre-cleared information such as NHPD Labelling Standards and Monographs as a tool to expedite applications
- Process improvements implemented in order to expedite Transitional DIN & Compensial applications
- Initial Assessment process for incoming Non-Traditional applications now occurring within weeks of receipt

This report and future versions will include detailed information regarding status of notifications and amendments which are applications made to NHPD in order to modify a licensed product.

Quarter 3 (October 1, 2009 to December 31, 2009)

During this quarter, a total of 3619 PLAs were completed, 64.0% (2315) of these completions resulted in product licences, 25.5% (924) were refusals and the remaining 10.5% (380) of completions were as a result of the applicant withdrawing the application.

Of the 924 applications refused this quarter, the reasons were as follows:

- 50% were refused when applicants did not respond to a request for further information.
- 34% failed to meet basic application requirements.
- 9% were refused when the applicant's response to a request for further information did not meet the requirements.
- 3% did not meet the definition of a NHP.
- 3% were refused when quality, safety and/or efficacy issues were identified.
- 1% were refused as a result of significant changes having been made to the product itself in response to a request for further information (i.e. an "unsolicited change").

Highlights

2315

NHPs licensed
during Quarter 3

924

PLAs refused
during Quarter 3

380

PLAs withdrawn
during Quarter 3

Quarter 3 Statistics (October 1, 2009 to December 31, 2009)

Chart 1 – Total Number of Product Licence Applications (PLAs) Received and Completed during Quarter 3

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

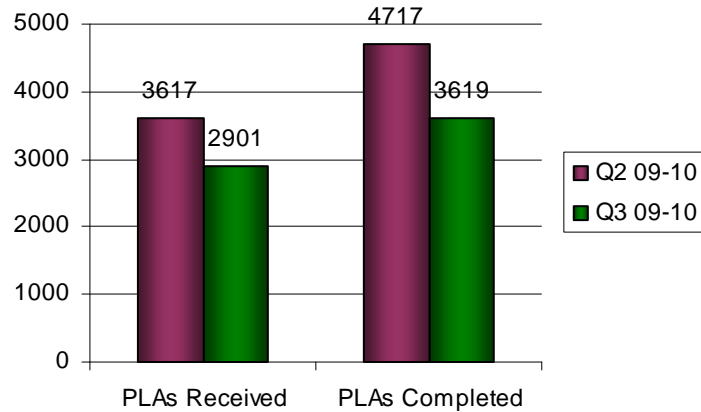


Chart 2 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 3 (Licensed, Refused or Withdrawn)

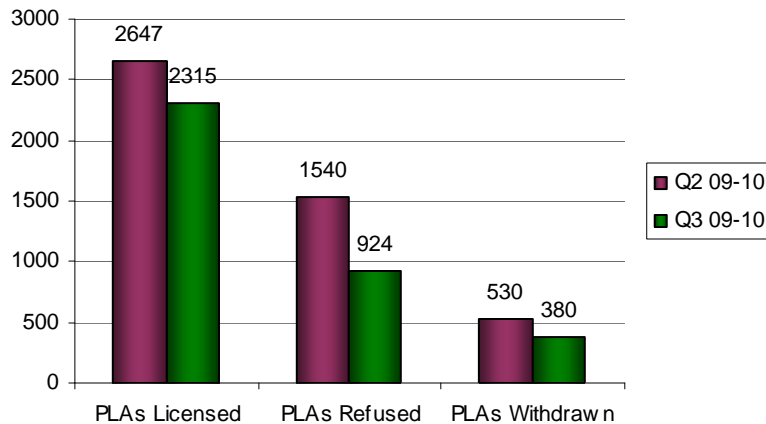


Chart 3 – Total Number of Product Licence Applications (PLAs) Completed during Quarter 3 (by Year of Application)

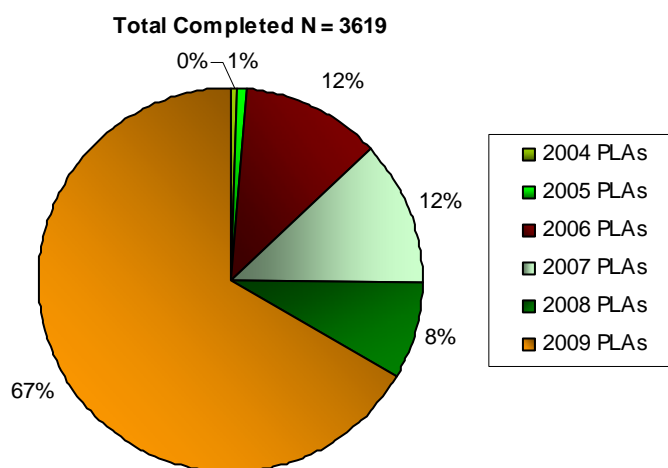
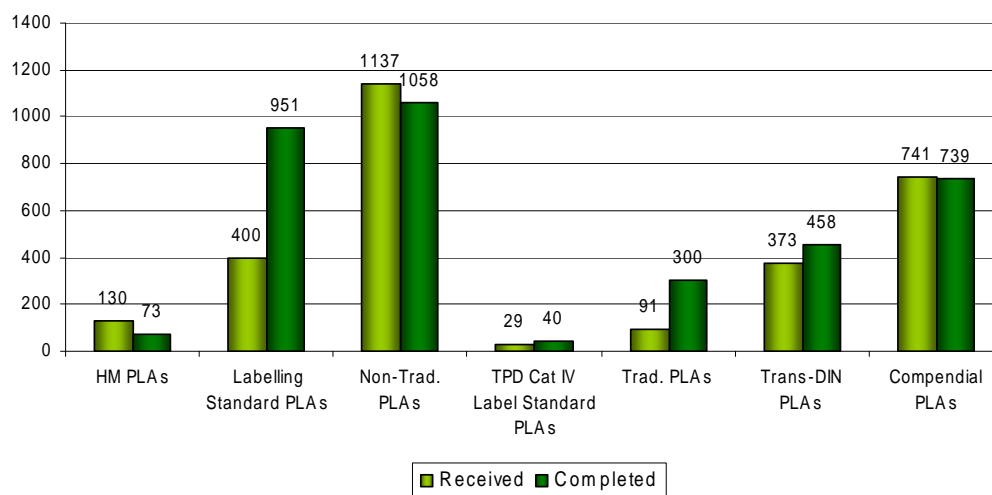


Chart 4 – Total Number of Product Licence Applications (PLAs) - by application type - Received and Completed during Quarter 3

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 Received and Completed during Quarter 3

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

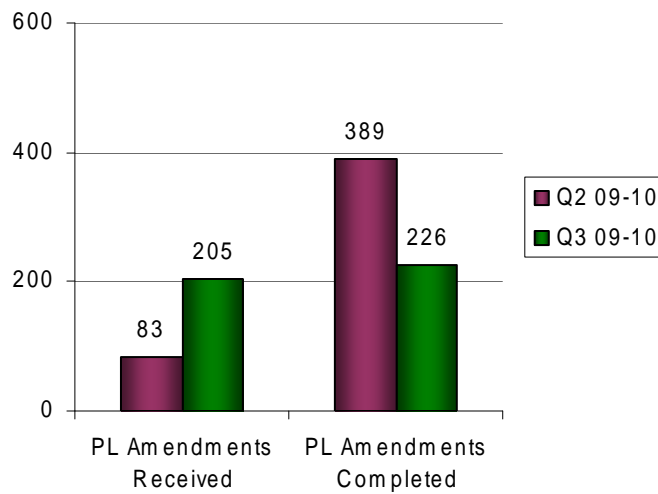


Chart 6 – Total Number of Product Licence (PL) Notifications Received and Completed during Quarter 3

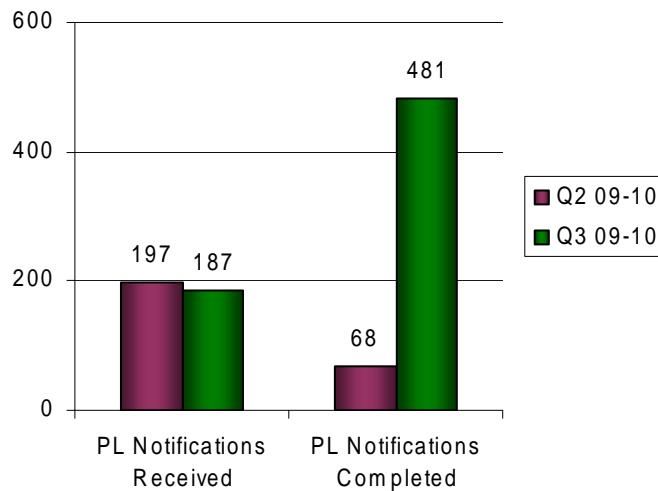


Chart 7 – Total Number of Site Licence Applications (SLAs) Received and Completed during Quarter 3

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

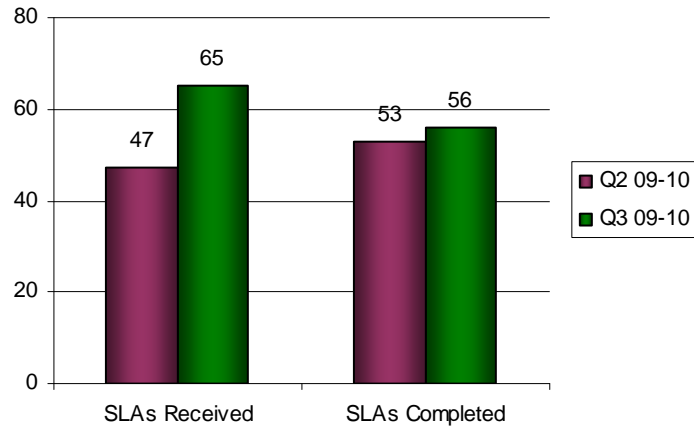
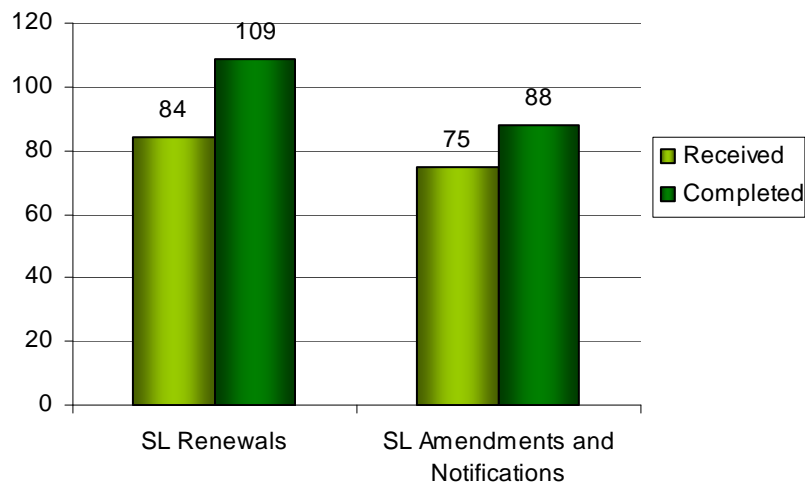


Chart 8 – Total Number of Site Licence (SL) Amendments, Notifications and Renewals Received and Completed during Quarter 3

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 12,976 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 4102 PLAs, signalling a reduction of 68.4% from the original 12,976 PLAs. As mentioned earlier in this report, the total number of backlog applications has risen to 12,976 from 12,635 as 341 NHPs in food format are now considered part of backlog. These applications are categorized as Non-Traditional and were previously not included in NHPD application statistics.

Highlights

68%

reduction of the backlog

94%

of backlog PLAs have been addressed

Table 1: Total “Backlog” PLAs as of December 31, 2009

Table 1 provides figures on the current status of the PLA “backlog”. Please note these numbers do not include amendments or notifications.

Status	Number	% of Total (12,976)
Licensed	2872	
In Licensing – administrative processing required	44	
Refused	3166	
To Be Refused – administrative processing required	304	
Withdrawn by applicant	2488	
Addressed PLAs - Completed	8874	68.4%
Has received one or more Information Request Notice (IRN) or E-IRN	2727	
Halted pending internal decision related to safety or efficacy	616	
Addressed PLAs – Received one or more IRN or E-IRN	3343	25.8%
Require Initial Assessment to determine if file requires E-IRN	111	
To receive E-IRN	6	
Awaiting or undergoing full review	296	
Halted pending internal decision related to safety or efficacy	331	
Miscellaneous Administrative Issues	15	
Non-Addressed PLAs	759	5.8%

Table 2: Total “Regular Workload” PLAs as of December 31, 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 or notifications.

Status	Number	% of Total (18,389)
Licensed	9046	
In Licensing – administrative processing required	130	
Refused	2653	
To Be Refused – administrative processing required	84	
Withdrawn by applicant	455	
Addressed PLAs – Completed	12368	67.3%
Has received one or more Information Request Notice (IRN) or E-IRN	1843	
Halted pending internal decision related to safety or efficacy	91	
Addressed PLAs – Received one or more IRN or E-IRN	1934	10.5%
Applications (all types) recently received at NHPD	462	
Require Initial Assessment to determine if file requires E-IRN	1208	
To receive E-IRN	25	
Awaiting or undergoing full review	1843	
Halted pending internal decision related to safety or efficacy	534	
Miscellaneous Administrative Issues	15	
Non-Addressed PLAs	4087	22.2%

Update on Amendments and Notifications

Since January 2004, NHPD has received 1206 notifications and 1412 amendments. NHPD has completed 99% of notifications and 83% of amendments to date.

Of the amendments that have been completed, 93.1% resulted in a revised product licence, 1.4% resulted in a refusal and 5.5% were withdrawn by the licensee.

Of the 246 amendments yet to be completed, 9 are considered to be in backlog and 237 are considered regular workload. Table 3 provides figures on the current status of amendments which were received on or after April 1, 2008 and are therefore not considered "backlog".

Table 3: Total "Regular Workload" Amendments as of December 31, 2009

Status	Number	% of Total (1058)
Licensed	704	
In Licensing – administrative processing required	70	
Refused	8	
To Be Refused – administrative processing required	1	
Withdrawn by applicant	38	
Addressed Amendments – Completed	821	78%
Has received one or more Information Request Notice (IRN) or E-IRN	63	
Addressed Amendments – Received one or more E-IRN or IRN	63	6%
Applications recently received at NHPD (in processing)	3	
Awaiting or undergoing full review	143	
Miscellaneous Administrative Issues	28	
Non-Addressed Amendments	174	16%

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
Abbreviated Labelling Standard (AbLS):	Document created by NHPD outlining information about the established safety and/or efficacy of a product or ingredient
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
Traditional Process Improvement Project:	Project initiated by NHPD, in 2009, which involves screening Traditional applications for critical evidence deficiencies through an initial assessment process
Regular workload:	All PLAs received on or after April 1, 2008