

# Status of Submissions Quarterly Report

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**Quarter 3**  
(October 1, 2008 to December 31, 2008)

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

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The *Status of Submissions 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.

The *Status of Submissions Quarterly Report* is released every quarter to the Canadian public via the NHPD's electronic bulletin. Subscribe to the NHPD e-bulletin at **[www.healthcanada.gc.ca/nhpd\\_bulletin](http://www.healthcanada.gc.ca/nhpd_bulletin)**

### **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 Submissions Quarterly Report* may be addressed to **[NHPD\\_DPSN@hc-sc.gc.ca](mailto: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, Health Canada has received 33,312 Product Licence Applications (PLAs). Of this total, over **20,500 PLAs have been completed, including the issuance of 10,344 Product Licences.**

### Reasons for Refusal

During the past quarter, a total of 1920 PLAs were completed, of which 394 were refused for the following reasons:

- 35% of PLAs failed to meet basic application requirements.
- 32% of PLAs were refused when applicants did not respond to a request for further information.
- 24% PLAs were refused when the applicant's response to a request for further information did not meet the requirements.
- 3% were refused when significant changes were made to the product itself in response to a request for further information (i.e. an "unsolicited change").
- 5% did not meet the definition of a NHP.

### Status Update on the Product Licence Application Backlog

As defined by the NHPD, the backlog consists of all PLAs received before April 1, 2008 which were incomplete as of that date. "Incomplete" includes PLAs for which the NHPD had not rendered a regulatory decision (i.e. the PLA was not licensed, withdrawn or refused) by April 1, 2008. All other PLAs received 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.

Health Canada has set a performance goal to address 60% of the total PLA backlog by March 31, 2009. The remaining 40% will be addressed by March 31, 2010.

As of April 1, 2008, the backlog consisted of 12,635 PLAs. Since that time, with the implementation of the new simplified Information Request Notice (IRN) process and other improvement initiatives, the backlog now numbers 8741 PLAs, a reduction of 33%.

Of the remaining PLAs in backlog, significant progress is being made on completing the assessment of these files. The majority of the PLAs in backlog are actively being reviewed and companies are engaged through Information Request Notices (IRN). In some cases, the NHPD is awaiting further information from a company in order to proceed with the submission.

The table below provides figures on the current status of the PLA backlog.

#### Highlights

**10,344**

NHPs licensed since 2004

**20,517**

PLAs completed since 2004

#### Highlights

**33%**

Reduction of the backlog.

**100%** of PLAs

have been issued submission numbers.

**73%** of PLAs

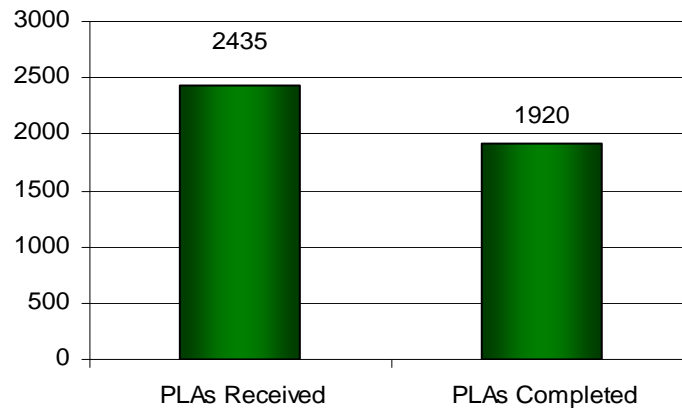
have undergone an initial assessment against the evidence criteria and/or are undergoing a full assessment of their safety, efficacy and quality.

<b>Total Backlog</b>	<b>12,635 PLAs</b>	
Status	Number	Percentage of Total Backlog
<b>Completed PLAs</b>	<b>4176 PLAs</b>	<b>33%</b>
• <i>Licensed</i>	1921	15%
• <i>Refused</i>	1609	12%
• <i>Withdrawn</i>	646	5%
<b>Outstanding (Remaining Backlog)</b>	<b>8741 PLAs</b>	<b>67%</b>
• <i>Undergoing an initial assessment against the evidence criteria.</i>	3739	29.6%
• <i>Have been placed in the appropriate review stream and are awaiting a full assessment of their safety, efficacy and quality (this includes PLAs that have undergone an initial assessment against the evidence criteria).</i>	2990	23.7%
• <i>Undergoing a full assessment of safety, efficacy and quality.</i>	1730	13.7%

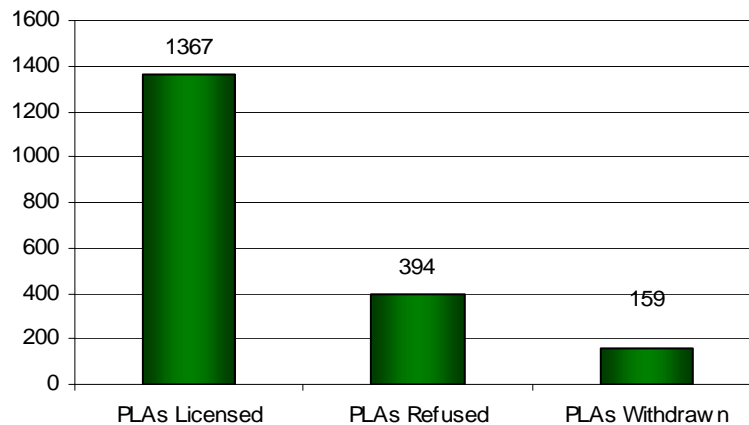
## Statistics

**Chart 1 – Total Number of Product Licence Applications (PLAs) Received and Completed for Quarter 3 (October 1, 2008 to December 31, 2008).**

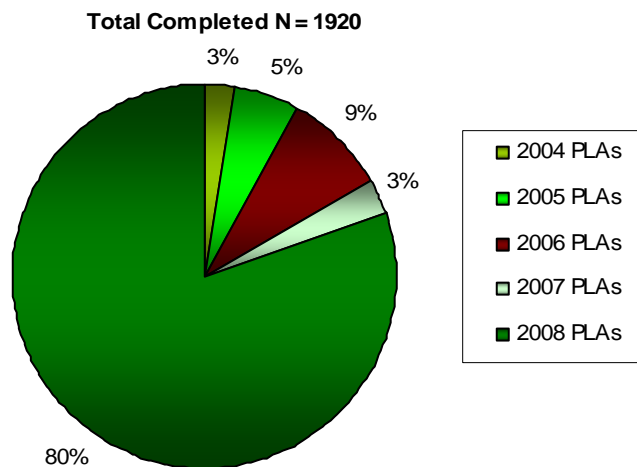
Note – “Completed” includes all submissions that were licensed, refused or withdrawn by the applicant.



**Chart 2 – Total Number of Product Licence Applications (PLAs) Licensed, Refused and Withdrawn for Quarter 3 (October 1, 2008 to December 31, 2008).**

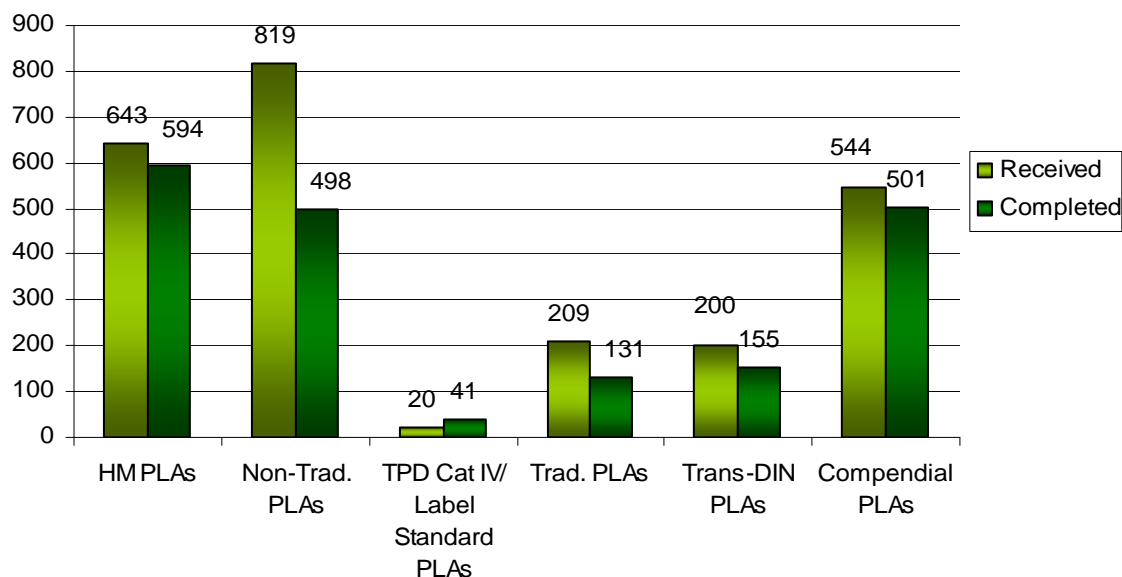


**Chart 3 – Total Number of Product Licence Applications (PLAs) Completed by Year of Application for Quarter 3 (October 1, 2008 to December 31, 2008).**



**Chart 4 – Total Number of Product Licence Applications (PLAs) Received and Completed for Quarter 3 (October 1, 2008 to December 31, 2008).**

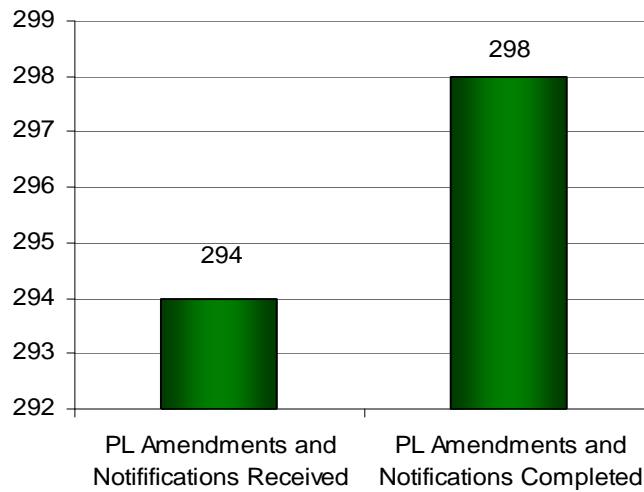
Note – “Completed” includes all submissions that were licensed, refused or withdrawn by the applicant.



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

**Chart 5 – Total Number of Product Licence Amendments and Notifications Received and Completed for Quarter 3 (October 1, 2008 to December 31, 2008).**

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



\* Refer to Appendix A for definitions of acronyms found in Chart 5.

**Chart 6 – Total Number of Site Licence Applications (SLAs) Received and Completed for Quarter 3 (October 1, 2008 to December 31, 2008).**

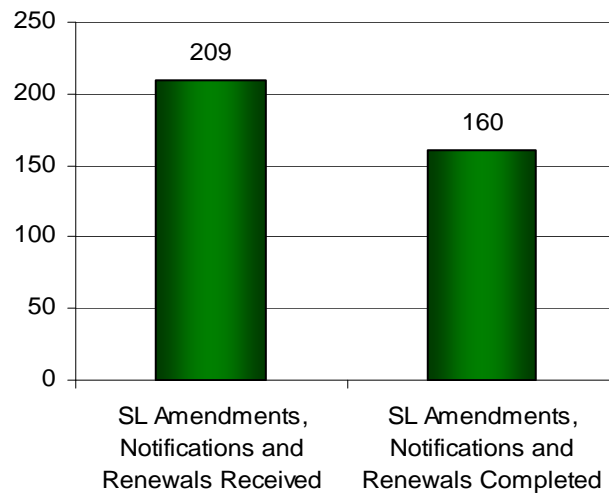
Note – “Completed” includes all submissions that were licensed, refused or withdrawn by the applicant.





**Chart 7 – Total Number of Site Licence Amendments, Notifications and Renewals Received and Completed for Quarter 3 (October 1, 2008 to December 31, 2008).**

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



\* Refer to Appendix A for definitions of acronyms found in Chart 7.

## 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>