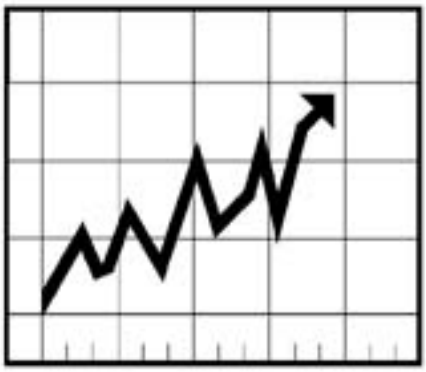
Health Canada Santé Canada



Status of Applications Quarterly Report

Quarter 2

(July 1, 2011 to September 30, 2011)

Canada

Status of Applications Quarterly Report

Quarter 2 (July 1, 2011 to September 30, 2011)

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 licence, site licence and clinical trial applications received and processed by 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 **PLA.info.DLMM@hc-sc.gc.ca**.

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Performance Summary and Highlights

Format and content of report

NHPD's Quarterly Report reflects the coming into force of the *Natural Health Products (Unprocessed Product Licence Applications) Regulations* (NHP-UPLAR) on August 4, 2010 and the publication of performance targets related to Product Licence Applications (PLAs) in the NHPD Application Management Policy on August 9, 2010.

NHPD reports on two types of product licence applications:

1. applications received before NHP-UPLAR came into force (pre-UPLAR PLAs), and
2. applications received after NHP-UPLAR came into force (post-UPLAR PLAs).

Overall Product Licence Application Statistics Summary

NHPD has received 64,318 PLAs from January 1, 2004 to September 30, 2011. Of this total, **55,122 (86%) PLAs have been completed, including the issuance of 30,389 Product Licences representing 42,297 products.** The remaining completed applications were either refused by NHPD or withdrawn by the applicant. In total, 1545 companies have received a product licence to date.

Pre-UPLAR Product Licence Application Statistics Summary

Of the 10,885 PLAs and amendments received before August 5th, 2010 (pre-UPLAR PLAs) and which had not been completed prior to that date, 4,060 (37%) have now been completed. NHPD is committed to completing the remaining 6,825 applications before NHP-UPLAR is repealed in February 2013.

Post-UPLAR Product Licence Application Statistics Summary

Of the 12,124 applications and amendments received on and after August 5th, 2010 (post-UPLAR PLAs), 48% fully meet NHPD's pre-cleared information (60 day review target) and the remaining 52% require full assessment (180 days review target).

During Quarter 2, NHPD met performance targets as follows:
30 day initial assessment: 90%
60 day pre-cleared information: 97%
180 day full assessment: 95%

Overall Site Licence Application Statistics Summary

NHPD has received 1863 Site Licence Applications (SLAs) from January 1, 2004 to September 30, 2011. Of this total, 1818 (98%) SLAs have been completed, including the issuance of 1230 Site Licences. The remaining completed applications were either refused by NHPD or withdrawn by the applicant. A total of 2289 Site Licence Renewals have been received for issued Site Licences. 97% of all Site Licence Renewals have been completed.

During Quarter 2, NHPD received 34 SLAs and 106 Site Licence Renewals and completed 36 SLAs and 86 Site Licence Renewals.

Overall Clinical Trial Application Statistics Summary

From January 1, 2004 to September 30, 2011, NHPD has received 355 Clinical Trial Applications (CTAs). Of this total, 342 (96%) CTAs have been completed, including the issuance of 293 Notices of Authorization. The remaining completed applications were either refused by NHPD or withdrawn by the applicant. A total of 297 CTA Amendments and Notifications have been received for issued Notices of Authorization. 98% of all CTA Amendments and Notifications have been completed.

During Quarter 2, NHPD received 7 CTAs and 12 CTA Amendments and completed 18 CTAs and 16 CTA Amendments.

Quarter 2 (July 1, 2011 to September 30, 2011)

During this quarter, a total of 2270 PLAs were completed, 60% (1366) of these completions resulted in product licences, 32% (722) were refusals and the remaining 8% (182) of completions were as a result of the applicant withdrawing the application.

Highlights

1366
NHPs licensed during Quarter 2

722
PLAs refused during Quarter 2

182
PLAs withdrawn during Quarter 2

Of the 722 applications refused this quarter, the reasons were as follows:

- 61% failed to meet basic application requirements.
- 20% were refused when applicants did not respond to a request for further information.
- 6% were refused when quality, safety and/or efficacy issues were identified.
- 5% were refused when the applicant's response to a request for further information did not meet the requirements.
- 5% were refused for containing an ingredient not listed in the Natural Health Products Ingredient Database (NHPID).
- 2% 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").
- 1% did not meet the definition of a NHP.

Unacceptable Applications

Since June 2009, certain applications are returned to applicants via regular mail if they are deemed to be unacceptable for processing, as referenced in section 7.2 of NHPD's Application Management Policy. These applications are accompanied by a Rejection Notice – Administrative Deficiency. NHPD reports on these applications by stating the total number of unacceptable application packages and the reasons for rejection.

During this quarter, a total of 15 product licence applications were deemed unacceptable and were not included in total product licence application statistics.

Of the 15 applications deemed unacceptable for processing this quarter, the reasons were as follows:

- 47% third party did not have authorization to sign on behalf of a company
- 13% missing the application type
- 13% missing signature
- 13% contact information was not provided or incomplete
- 7% missing Canadian Representative information
- 7% missing medicinal/non medicinal information (ie. ingredients were not submitted with application)

Quarter 2 Statistics (July 1, 2011 to September 30, 2011)

Chart 1 – Total Number of PLAs Received and Completed during Quarter 2 compared to Quarter 1

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

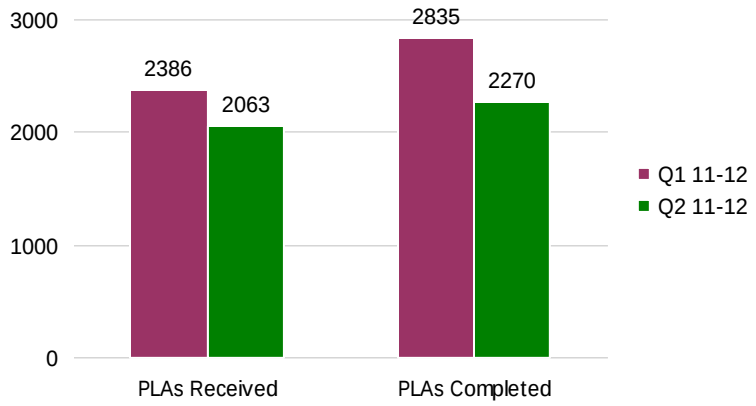


Chart 2 – Total Number of PLAs Completed during Quarter 2 compared to Quarter 1 (Licensed, Refused or Withdrawn)

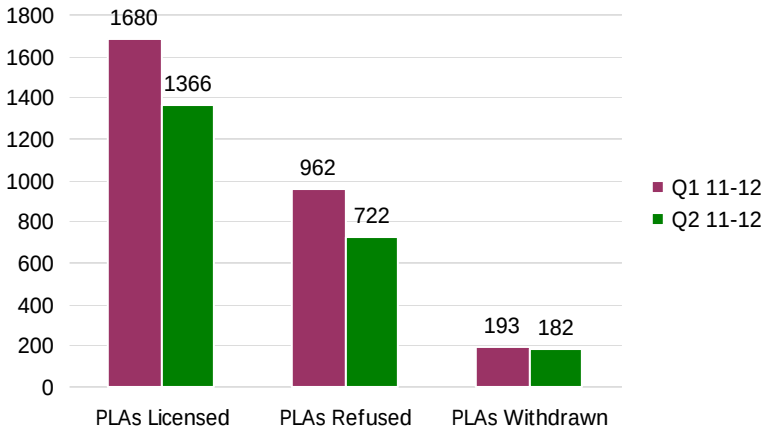


Chart 3 – Total Number of PLAs Completed during Quarter 2, Pre vs. Post UPLAR (n=2270)

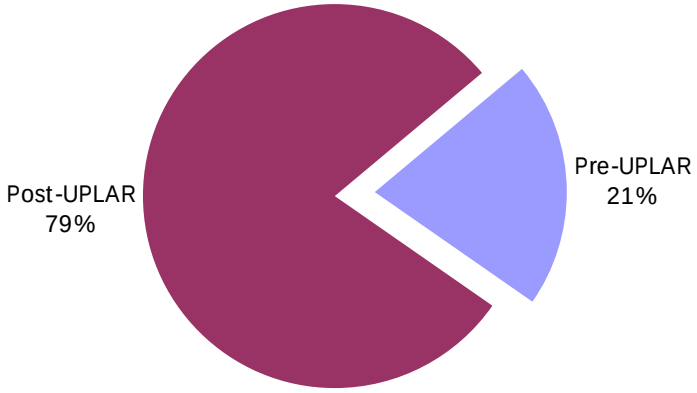
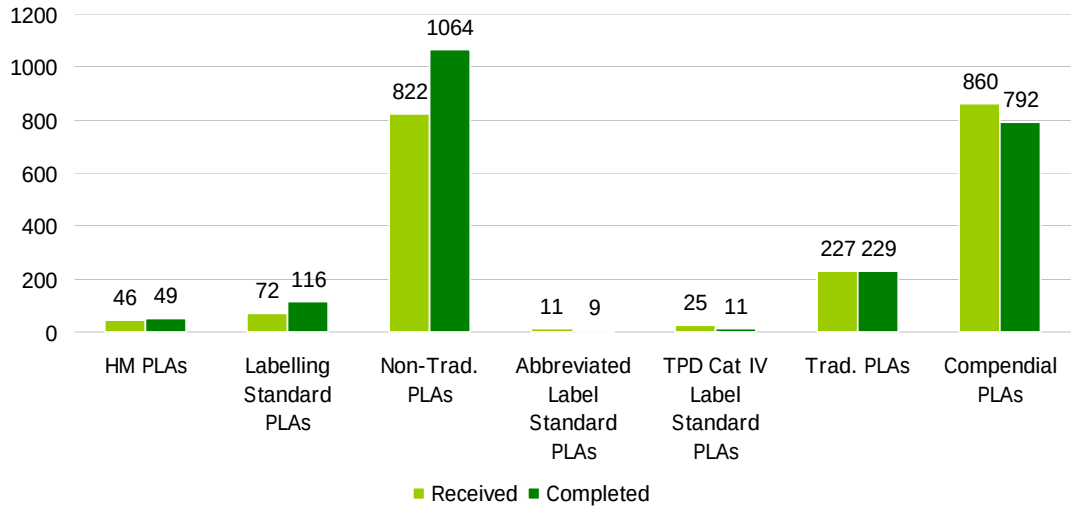


Chart 4 – Total Number of PLAs - by application type -Received and Completed during Quarter 2

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 Received and Completed during Quarter 2 compared to Quarter 1

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

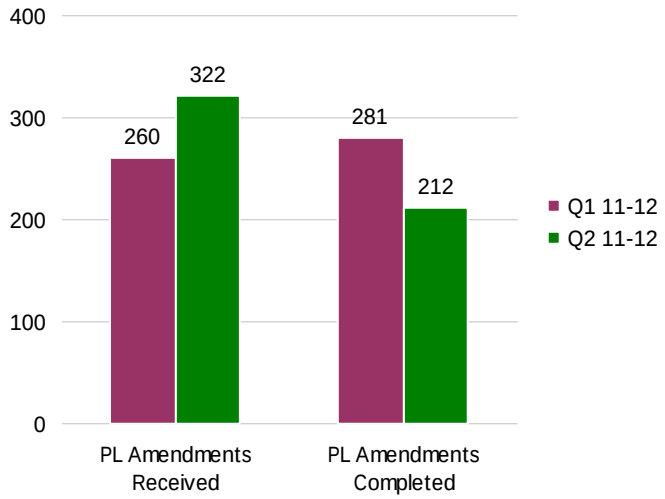


Chart 6 – Total Number of Product Licence (PL) Notifications Received and Completed during Quarter 2 compared to Quarter 1

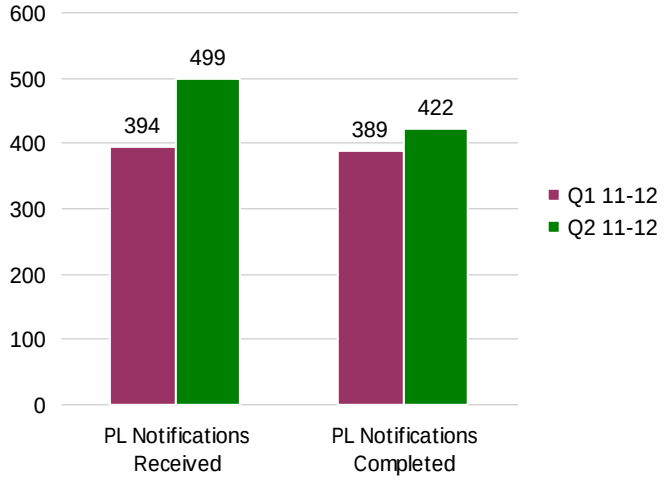


Chart 7 – Total Number of Site Licence Applications (SLAs) Received and Completed during Quarter 2 compared to Quarter 1

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

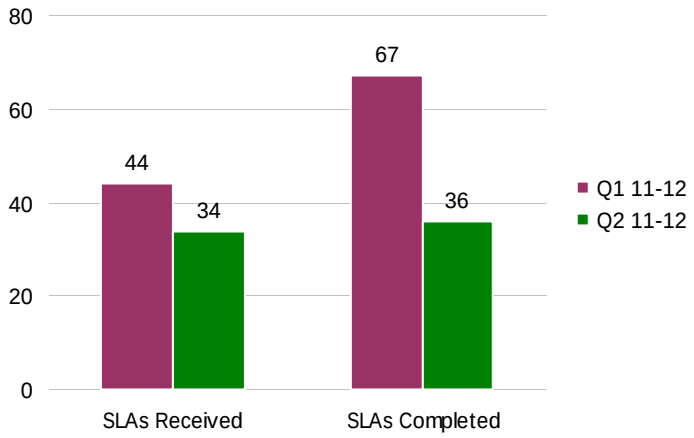
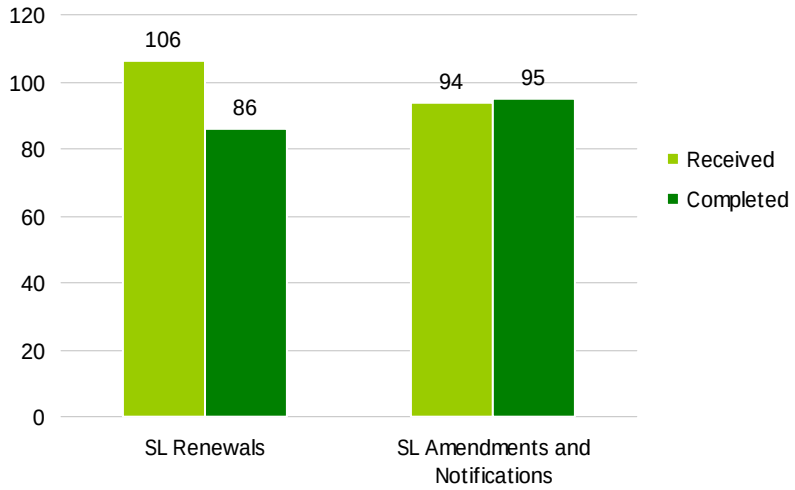


Chart 8 – Total Number of Site Licence (SL) Amendments, Notifications and Renewals Received and Completed during Quarter 2

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



Update on PLAs received before August 5, 2010 (pre-UPLAR)

This section provides figures on the current status of PLAs which were received before August 5, 2010 and not complete as of that date. All applications received after this date will be measured against NHPD's performance targets (see Tables 2-5). These performance targets were communicated to applicants via the NHPD Application Management Policy. Please note these numbers also include product licence amendments.

As shown in Table 1 below, the number of applications remaining at NHPD as of August 5, 2010 was 10,885. The number remaining as of September 30, 2011 is 6,825. The objective is to complete the remaining 6,825 before NHP-UPLAR is repealed in February 2013. At the same time, NHPD will be focused on completing all applications received on or after August 5, 2010 in accordance with the performance targets communicated in the Application Management Policy.

Table 1: Total Product Licence Applications and Amendments received before August 5, 2010 which were not complete as of that date

Status	Number	% of Total (10,885)
Licensed	1959	
In Licensing – administrative processing required	22	
Refused	1414	
To Be Refused – administrative processing required	19	
Withdrawn by applicant	646	
Total Completed	**4060**	**37.3%**
Full Assessment in progress	719	
With Applicant pending response to IRN	1171	
Total Undergoing Full Assessment	**1890**	**17.4%**
In Queue for Full Assessment	2915	
Initial Assessment not yet completed	83	
Total In Queue for Full Assessment	**2998**	**27.5%**
Halted[1] pending internal decision related to safety or efficacy	1888	
Miscellaneous Administrative Issues	49	
Total Other	**1937**	**17.8%**

[1] Halted applications include those containing energy drinks, nhps in food format, aromatherapy products and weight loss / weight management products. Recently resolved halted issues include enzymes and probiotics.

Chart 9 – Pre-UPLAR Applications Not Complete by Application Type (n = 6825)

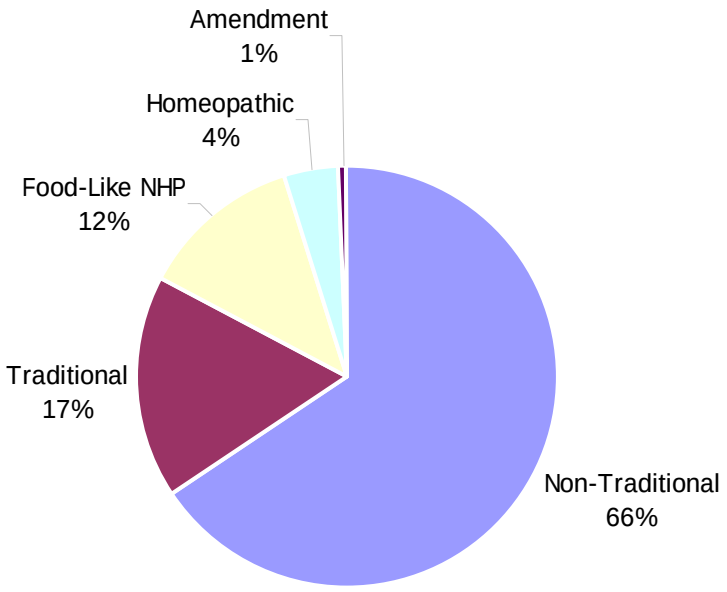
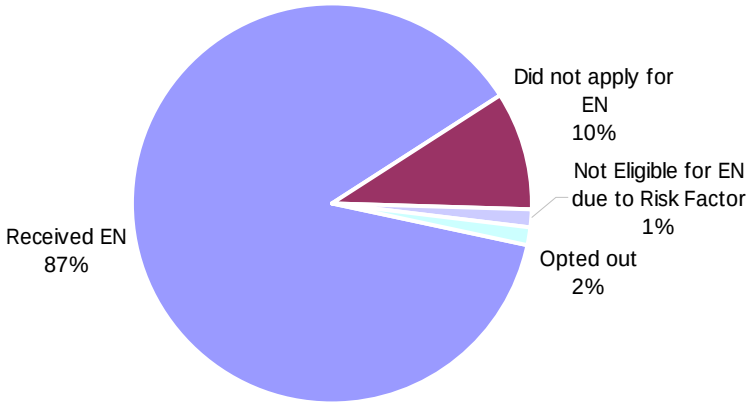


Chart 10 – Pre-UPLAR PLAs Not Complete: Ability to Sell (n = 6786)



Update on PLAs received on or after August 5, 2010 (post-UPLAR)

This section provides figures on the current status of PLAs which were received on or after August 5, 2010. All applications received after this date will be measured against NHPD's performance targets. These performance targets were communicated to applicants via the NHPD Application Management Policy. Please note these numbers also include product licence amendments.

For the purposes of the performance targets, these applications are separated into two categories: those which fully meet pre-cleared information and those which require full assessment of safety, efficacy and / or quality information. Pre-cleared information includes NHPD Monographs, Labelling Standards and Abbreviated Labelling Standards. Products falling within the parameters described in these documents are subject to shorter review times. See Appendix A for the definition of pre-cleared information.

Applications fully meeting pre-cleared information (60 day review target)

The performance on these applications is outlined in Table 2 below. For these types of applications, NHPD has consistently met the 60-day performance target for some time and continues to do so. Please note that this Table only includes amendments supported by pre-cleared information.

Table 2: PLAs and Amendments completed in Quarter 2 that fully meet Pre-Cleared Information

Application Type	Completed	% Completed within 60 days
Compendial	791	98%
Labelling Standards	110	98%
Abbreviated Labelling Standards	9	88%
Amendments	116	90%
Total	**1026**	**97%**

Of the 388 applications still in progress, 97% were received less than 60 days ago.

Applications requiring full assessment of safety, efficacy and / or quality information (30 day review target for Administrative Processing and Initial Assessment)

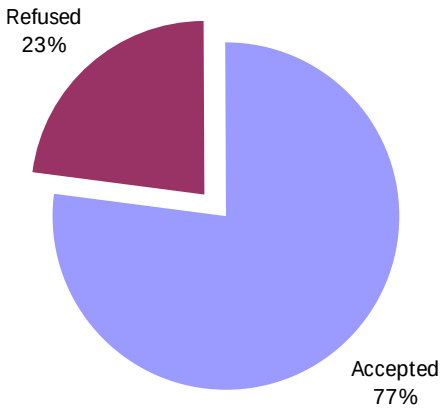
For these types of applications, NHPD's objective is to perform the administrative processing and initial assessment within a 30 day timeframe as described in the Application Management Policy. This 30 day target applies only to applications and amendments received on or after August 5, 2010. At the end of the 30 day timeframe, applicants receive an Application Acceptance Letter or a Notice of Refusal – Initial Assessment. In some cases, the application may be withdrawn by the applicant during the 30 day period. The performance on these applications is outlined in Table 3 below.

This quarter, 1262 applications, which require full assessment of safety, efficacy and / or quality information, received an Application Acceptance Letter or decision. In 90% of cases, this was completed within the 30 day target.

Table 3: Breakdown of PLAs and Amendments for which an Application Acceptance Letter or decision was issued during Quarter 2

Action	Count	% Completed within 30 days
Application Acceptance Letter issued	944	91%
Notice of Refusal – Initial Assessment issued	284	86%
Withdrawn by the Company	34	94%

Chart 11 – Initial Assessment in Quarter 2: Acceptance versus Refusal (n=1228)



Of the 376 applications which have not yet received an Application Acceptance Letter or decision, 90% were received less than 30 days ago.

Applications which require full assessment of safety, efficacy and / or quality information (180 day review target for Full Assessment)

For these types of applications, NHPD's objective is to meet the 180 day review target as described in the Application Management Policy. This 180 day target applies only to applications and amendments received on or after August 5, 2010 that have been issued an Application Acceptance Letter. This quarterly report provides more detail in regards to the 180 day timeline and the percentage of applications completed within that timeline.

This quarter, NHPD completed 666 applications requiring full assessment of safety, efficacy and / or quality. In 95% of cases, this was completed within the 180 day target.

Table 4: Breakdown of PLAs and Amendments which require full assessment that were completed during Quarter 2

Action	Count	% Completed within 180 days
Product Licence Issued	480	98%
Notice of Refusal – Full Assessment	152	94%
Withdrawn by the Company	34	65%

Currently, there are 1747 applications which require full assessment that have been accepted and are currently in progress. 462 have exceeded 180 days. In 94% of cases (433 applications), this was as a result of a halted[1] issue.

[1] Halted applications include those containing energy drinks, nhps in food format, aromatherapy products and weight loss / weight management products. Recently resolved halted issues include enzymes and probiotics.

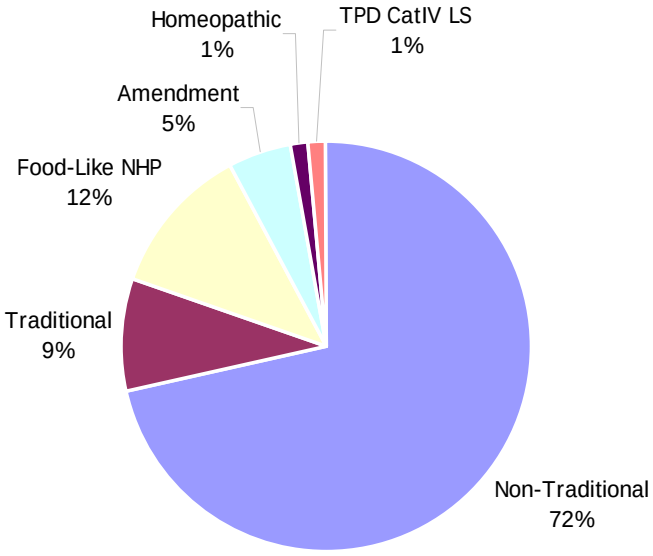
Table 5 outlines the status of the 4118 PLAs received after August 5, 2010 that were issued an Application Acceptance Letter and are therefore subject to NHPD's 180 day performance target for full assessment as outlined in the Application Management Policy.

Table 5: Status of all PLAs and Amendments received after August 5, 2010 which have received an Application Acceptance Letter

Status	Number	% of Total (4118)
Licensed	1623	
In Licensing – administrative processing required	96	
Refused	612	
To Be Refused – administrative processing required	9	
Withdrawn by applicant	136	
Total Completed	**2476**	**60.1%**
Has received at least one request for further information	596	
Full Assessment in progress	458	
Total In Full Assessment	**1054**	**25.6%**
Halted[1] pending internal decision related to safety or efficacy	588	
Total Halted	**588**	**14.3%**

[1] Halted applications include those containing energy drinks, nhps in food format, aromatherapy products and weight loss / weight management products. Recently resolved halted issues include enzymes and probiotics.

Chart 12 – Post-UPLAR PLAs not yet complete which have received an Application Acceptance Letter by Application Type (n = 1642)



Appendix A – Acronyms and Definitions

PL:	Product Licence
SL:	Site Licence
PLA:	Product Licence Application
SLA:	Site Licence Application
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. AbLS is one type of pre-cleared information.
Amendment:	Product Licence Application proposing revisions to an existing product licence
HM PLA:	Homeopathic Medicines Product Licence Application
Labelling Standard (LS):	Document created by NHPD outlining information about the established safety and efficacy of a type of product. LS is one type of pre-cleared information.
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
Compendial PLA:	Product Licence Application citing a monograph found in the NHPD's Compendium of Monographs
Application Management Policy:	The Application Management Policy outlines the way in which Product Licence Applications for natural health products are submitted in accordance with the *Natural Health Products Regulations*. The policy also outlines the responsibilities and expectations for natural health product applicants before and throughout the application review process. In addition, the policy outlines the proposed performance targets for the management of all types of product licence applications. This policy is available on NHPD's website and applies to all product licence applications submitted after August 5, 2010.

Completed:	When NHPD issues a Product Licence, Notice of Refusal or when the applicant withdraws their application, the application is considered to be "completed".
Halted:	An application which cannot be further processed due to the need for an internal decision related to safety and/or efficacy
Initial Assessment:	An assessment of the evidence in support of safety, efficacy and quality to ensure that the requisite information for the type of application in question, as defined in the *Natural Health Product Regulations* and as described in various guidance documents has been submitted. An Application Acceptance Letter is issued when the information and material submitted are deemed complete and are acceptable for full assessment. Alternatively, if deficiencies are identified during the initial assessment, a Refusal Letter - Initial Assessment will be issued. For applications received on or after August 5, 2010, this assessment is performed within 30 days of receipt of the application. This assessment is performed only for applications which require full assessment of safety, efficacy and / or quality information.
Information Request Notice (IRN):	A notice sent from NHPD to an applicant requesting additional information to support the safety, efficacy or quality of a product. As outlined in the Application Management Policy, this notice is sent during the Full Assessment stage and the applicant has 30 days to respond. Applicants can contact the Submission Coordinator indicated on the notice with questions or clarifications.
Natural Health Products (Unprocessed Product Licence Applications) Regulations:	Also referred to as UPLAR or NHP-UPLAR. These Regulations allow for certain products to be issued exemption numbers by Health Canada. In order to qualify, products must: have had a complete product licence application (PLA) submitted; not have been withdrawn; still be with Health Canada for a final licensing decision; and not fall within certain risk criteria. Products for which an exemption number is issued by Health Canada will be exempted from the current prohibition against sale without a product licence (as set out in s.4 of the *Natural Health Products Regulations*). In other words, these products can now be sold legally. These Regulations were registered on August 4, 2010 and will be repealed 30 months following that date on February 4, 2013.

Pre-Cleared Information:	Information which has been pre-cleared by the NHPD includes NHPD Monographs, Labelling Standards and Abbreviated Labelling Standards. These documents outline the parameters under which a product can be sold including allowable claims, dose limits and risk information required on the product label. If a company wishes to receive a licence and their product falls within the parameters of any of these documents, the licence can be issued in 60 days. Pre-cleared information can also be used to help support other applications types; for example, one ingredient within a multi-ingredient product may be supported by a monograph for that ingredient.
UPLAR:	See definition of *Natural Health Products (Unprocessed Product Licence Applications) Regulations* above.
Pre-UPLAR PLAs:	Product Licence Applications received prior to the publication of the *Natural Health Products (Unprocessed Product Licence Applications) Regulations* on August 5th, 2010 which were not yet complete as of that date
Post-UPLAR PLAs:	Product Licence Applications received on or after August 5th, 2010. These applications are subject to the performance targets set out in Application Management Policy.