Natural Health Product Licence Application Form User Manual

Canada

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1.0 Natural health product license application form overview

The Electronic Product Licence Application (ePLA) form is for Natural Health Product Licence Applications and for post-licence changes. The ePLA is designed to be completed on the applicant's workstation where it can be saved and retrieved at any time. Through an active Internet connection, the form can automatically access the Natural Health Products Ingredients Database (NHPID) to provide drop-down selections of medicinal and non-medicinal ingredients and related information.

This user manual provides the information on how to successfully complete the ePLA form. The Product Licensing guidance document explains the terminology and appropriate information to be included in a natural health product (NHP) licence application. This guidance document also outlines the application requirements and submission process for each NHP application type.

For additional information not provided in this user manual, please contact Natural Health Products Online Support.

2.0 Recommendations for optimal results

Following these recommendations will lead to optimal results when using the ePLA form.

2.1 General

Read through the entire user manual

While it may be strongly tempting to begin filling out the form right away, it is highly recommended to review this user manual first. This will enable you to gather the information you might need in advance in order to have it on hand when completing the form. It will also assist you in more quickly locating the answer you need should a question arise while completing the form.

Meet the system requirements

To use this electronic form associated with the Natural Health Products Online System most effectively, be sure that your workstation meets the System Requirements.

Use the latest version of the ePLA

The NHPD is regularly updating the ePLA form to add new features and to improve efficiency. New releases are announced in advance; however it is always a good practice to check the NHPD website regularly for the latest version of the ePLA. You must always save the ePLA to your workstation and never work on the version through the internet browser.

Configure the proper security settings

Your version of Adobe Reader or Acrobat may have default settings to provide heightened security for your work. However, some of these settings are incompatible

with the more advanced features of the NHPD electronic forms. As a result, you may see a yellow pop-up bar across the top of the form or a pop-up box with a message like:

"*Some features have been disabled to avoid potential security risks. Only enable these features if you trust this document*"
or
"*Error NotAllowedError: Security settings prevent access to this property or method"*.

To avoid these messages, please do the following:
Under the "***Edit***" menu, select "***Preferences***" and then "***Security (Enhanced)***"
Uncheck the "***Enable Enhanced Security***" box.

To avoid potential security issues with your PDF forms, please make the following adjustment to your version of Adobe Reader or Acrobat:
Under the "***Edit***" menu, select "***Preferences***" and then "***Trust Manager***"
Uncheck the box under "***PDF File Attachments***"

If you have concerns about making these changes to your security settings, consult with your IT security advisor first.

After doubling clicking on the form saved to your workstation, an initial screen will warn you that various connection tests will take place when you start the form. If any of these tests fail, it is most likely because of improper security settings.

Ensure Java Script is enabled

When Java script is not enabled in an ePLA, a number of errors or issues occur such as buttons not working, the inability to type in certain text fields, and the absence of French terms when the selected language is French, to name a few. To enable Java script, please make the following adjustments to your version of Adobe Reader or Acrobat:

> Under the "**Edit**" menu, select "**Preferences**" and then select "**Java Script**" from the "**Categories**" list. Check "**Enable Acrobat Javascript**" and click on the "***OK***" button to save.

If you have concerns with making these changes to your security settings, consult with your IT security advisor first.

Save your work frequently

The ePLA form is continually applying business rules to ensure that the information being captured is as accurate as possible. It is always a good idea to save your work from time to time (suggestion: as you leave a page of the form or every thirty minutes – whichever comes first). You can always open the saved form at a later time and resume your work.

Save two versions of your form

The NHPD recommends applicants save a copy of their ePLA prior to finalizing the form. This allows applicants to use the form as a template if they have similar products they wish to use, or if they need to make modifications to a refused file. The "***Modify***" button

in the ePLA should never be used to prepare a new application as this will result in a duplicate tracking number which can severely slow the processing of an application.

2.2 Specialized

Establish a checkpoint before beginning a significant task

By saving the ePLA form, closing it and then opening it again and saving ensuing work under another file name, you are establishing a copy of the form that can be reused should you wish to no longer continue with information entered later (example: you decide to use a different monograph). Recommended opportunities to establish these checkpoints are:

- After successfully completing Part 1;
- Before starting Part 4;
- After selecting a monograph in Part 4

Check for all potential errors before proceeding
After the information for a part has been entered, select the "***Continue***" button to validate the content. Where information is missing (e.g. a required field has not been filled), an error box will appear stating "Some required fields have not been filled" and each box where the error occurred will have a colored background. By scrolling through the part just completed, you can identify these text boxes that are in error. Be sure to review the entire part and correct each instance before selecting the "***Continue***" button again.

> **NOTE:** For all NHPD forms, required information fields are indicated by an * after the field label.

Become familiar beforehand with monographs you may wish to invoke

Before selecting an ingredient from a monograph in the ePLA, be sure to review the attributes of the monograph beforehand to understand any limitations on dosage forms, conditions of use, and especially dosage ranges. Please note that all monographs are found in the NHPID and that each ingredient that has a monograph is linked to the monograph in the NHPID's ingredient entry. You may find that another monograph more closely meets your needs or that no monograph supports the specifics of your product.

Customize label text as appropriate to your needs

The Label Text Editor (LTE) in Part 5 is a handy and reliable way to generate required regulatory label content directly from the information provided in the ePLA. If the customization features of the LTE are insufficient to produce the label information you need, then simply provide your own label separately or use the copy feature provided for the generated label prior to finalization.

NOTE: This recommendation may be especially relevant for Homeopathic application types.

3.0 Natural health electronic Product Licence Application form

3.1 Overview

Before using the electronic application form, it is very important to become familiar with the application types for natural health products (see the Product Licensing guidance document).

The ePLA Form is divided into five parts which are completed progressively. When Part 1 is completed, Part 2 is displayed and so on (see Figure 1 below.) A Part is completed successfully when the "***Continue***" button is selected and no errors are found. The "***Continue***" button then transforms into a "***Modify Form***" button, and the completed Part is locked to prevent further changes and the next Part is displayed.

To unlock a completed Part to make changes, select the "***Modify Form***" button. It will transform back into a "***Continue***" button and make previous Parts eligible for update.

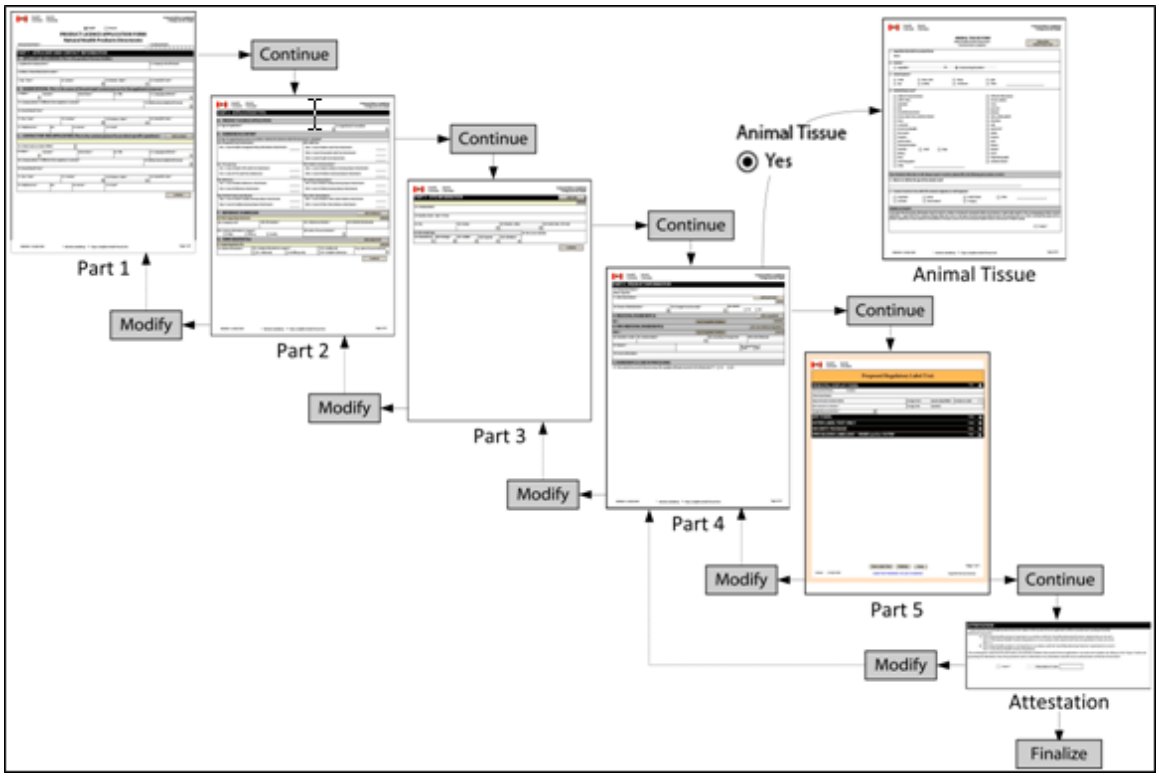
NOTE: Certain changes – such as returning to change the Type of Application in Part 2 after having begun to complete Part 4 – can have a major impact on any information already captured in Part 4. Because the form may not behave as intended, applicants should not go back and change the application type.

The ePLA Form may be saved at any time on the workstation and resumed at a later time.

Depending on the information captured in Part 4, additional forms may be appended automatically to the ePLA. If indicated that animal tissues were used in the processing of the product, or if an ingredient contains animal tissues, the Animal Tissue Form will automatically be added to the ePLA and will require completion.

TIP: The ingredients found in your product, both medicinal and non-medicinal, must be indicated as such in the Natural Health Products Ingredient Database prior to completing the ePLa.

Figure 1: Progressive assembly of an ePLA



For more information on completing Part 1 – Applicant and Contact Information, refer to Section 3.2

For more information on completing Part 2 – Application Type, refer to Section 3.3

For more information on completing Part 3 – Site Information, refer to Section 3.4

For more information on completing Part 4 – Product Information, refer to Section 3.5

For more information on completing Part 4 – Product Information for non-homeopathic applications, refer to Section 3.5.2

For more information on completing Part 4 – Product Information for homeopathic applications, refer to Section 3.5.3

For more information on completing Part 5 – Label Text, refer to Section 3.6

For more information on completing the Animal Tissue Form, refer to Section 3.7

For more information on finalizing the Product Licence Application, refer to Section 3.8

For more information on using the ePLA form after its submission, refer to Section 4

3.2 Applicant and contact information (Part 1)

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Applicant or licensee (Block 'a')

Figure 2: Applicant or licensee information

PART 1 - APPLICANT AND CONTACT INFORMATION		
A - APPLICANT OR LICENSEE (This is the product licence holder)		
Applicant/Company Name *		Company Code (if known)
Address: Street/Suite/Land Location *		City/Town *
Country *	Province/State	Postal Code/ZIP Code

Block A is to capture information about the company in whose name the Natural Health Product application is submitted and the product licence is to be registered (the applicant will be referred to as the licensee once a licence has been granted).

The Name, Street, City and Country are required in all cases. If the Country is "Canada" or "United States", the Province-State and the Postal/ZIP Code are required as well.

Postal/ZIP codes must be displayed in the appropriate format (*X#X #X#* or *#####*), where X represents a letter and # a number. Please make sure there are no trailing spaces in the Postal/ZIP Code or it will not pass validation.

Senior official (Block 'B')

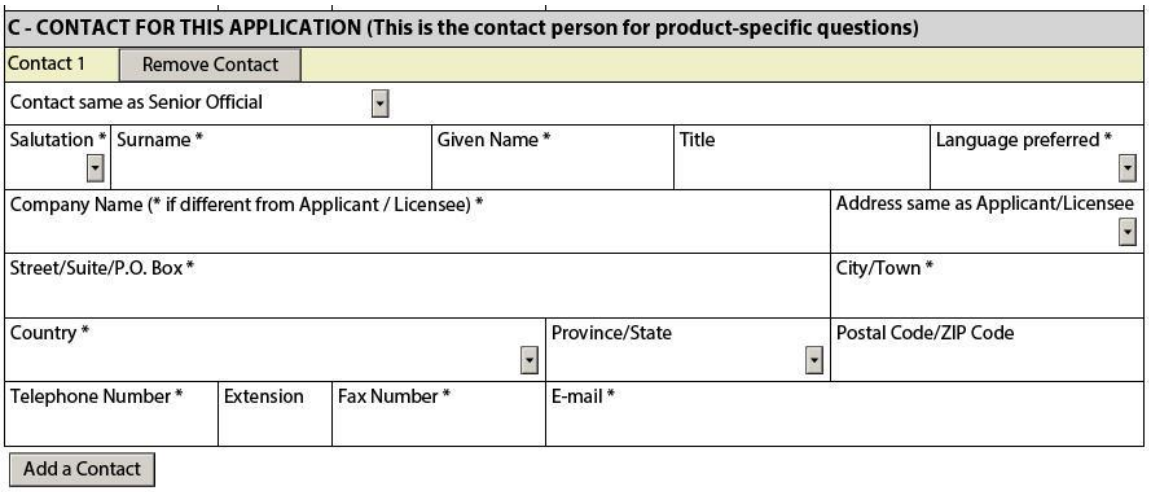
Figure 3: Senior official information

B - SENIOR OFFICIAL (This is the name of the principal contact person for the applicant/company)				
Salutation *	Surname *	Given Name *	Title	Language preferred *
Company Name (* if different from Applicant / Licensee) *				Address same as Applicant/Licensee
Street/Suite/P.O. Box *				City/Town *
Country *			Province/State	Postal Code/ZIP Code
Telephone Number *	Extension	Fax Number *	E-mail *	

A senior official must always be designated for the applicant company. The principal contact person for the licensee/applicant, at the address given, is the person to whom regulatory mail is sent. This is not the contact person for submission-specific questions, but the person who has the authority to represent the company.

Contact for this application (Block 'C')

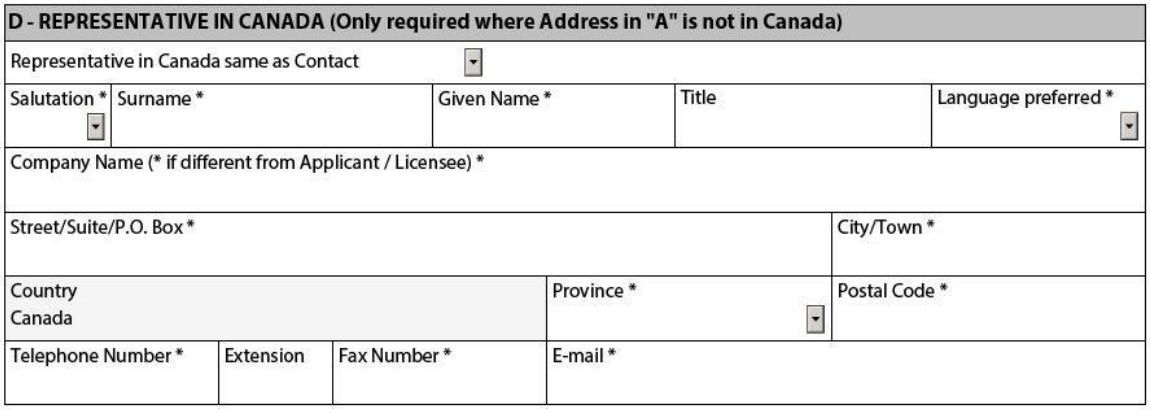
Figure 4: Contact for this application information



The contact for this application is the person to whom the NHPD will direct submission-specific questions. This may be an employee of the licensee/applicant, or an individual contracted from another company on behalf of the licensee/applicant (3rd party consultant). There may be more than one contact indicated per application. Additional contacts may be added by selecting the "***Add a Contact***" button.

Representative in Canada (Block 'D')

Figure 5: Representative in Canada information



The Representative in Canada block will be shown and is mandatory only if the Country indicated in the licensee/applicant's address (Block A) is not "Canada".

After the information has been entered, select the "***Continue***" button to validate the content of Part 1.

TIP: At this point, you may find it useful to save a version of the ePLA with a completed Part 1, which you can then reuse whenever you need to start a new application.

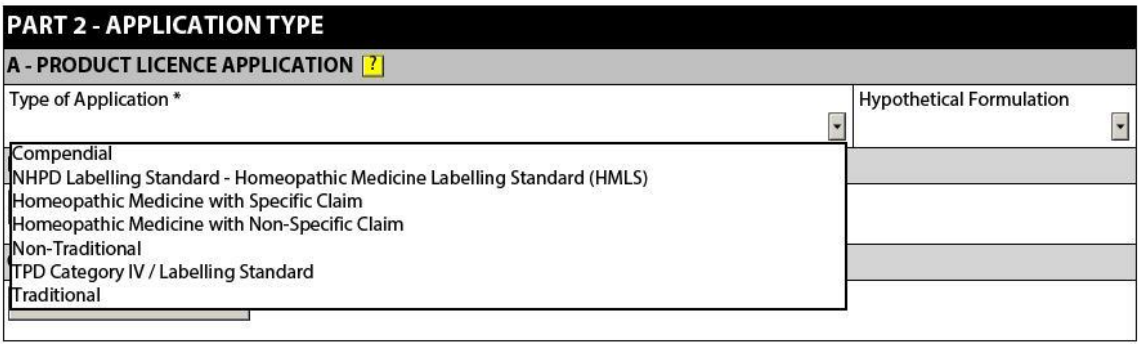
3.3 Application type (Part 2)

Product Licence Application (Block 'A')

The available types of application are as listed below and shown in Figure 6:

- Compendial
- NHPD Labelling Standard – Homeopathic Medicine Labelling Standard (HMLS)
- Homeopathic Medicine with Specific Claim
- Homeopathic medicine with Non-Specific Claim
- Non-Traditional
- TPD Category IV/Labelling Standard
- Traditional

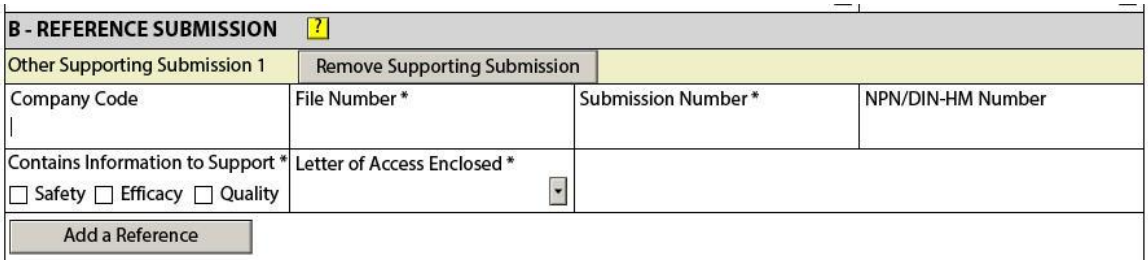
Figure 6: Example of type of application



Reference submission (Block 'B')

The Reference Submission block header is shown for all application types except for Compendial applications. To see the full block, click on the "***Add a Reference***" button. Where related submissions are referenced in the subject submission, provide the company code of the applicant/licensee of the reference submission, the file number, the submission number, and the NPN/DIN-HM number (if available). Indicate the summary report(s) being referenced by checking the appropriate box for safety, efficacy, and quality. A letter of access must be enclosed with the submission, as applicable.

Figure 7: Reference submission information

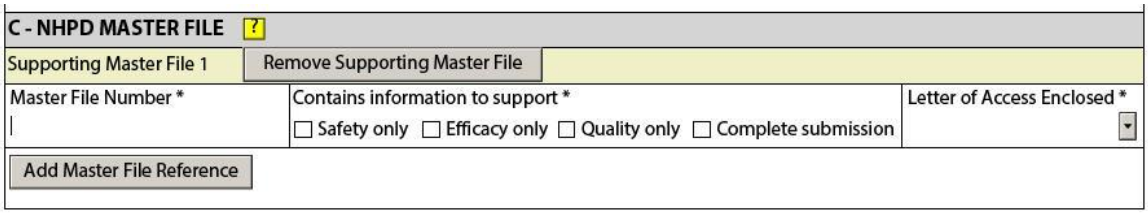


Should an applicant wish to reference more than one submission, selecting the "***Add a Reference***" button displays another Block F. Any of these blocks can be removed by clicking on the "***Remove Supporting Submission***" button.

NHPD master file (Block 'C')

The NHPD Master File block header is always shown. To see the full block, click on the "***Add Master File Reference***" button. Where related submission information is contained in a Master File, please indicate the Master File number, the information being supported (such as safety, efficacy, quality, or complete submission), and whether a letter of access is enclosed.]

Figure 8: Master file information



Should an applicant wish to reference more than one NHPD Master File, selecting the "***Add Master File Reference***" button displays another Block G. Any of these blocks can be removed by clicking on the "***Remove Supporting Master File***" button.

For more information on Natural Health Products Directorate Master Files, please refer to the Master File Procedures Guide.

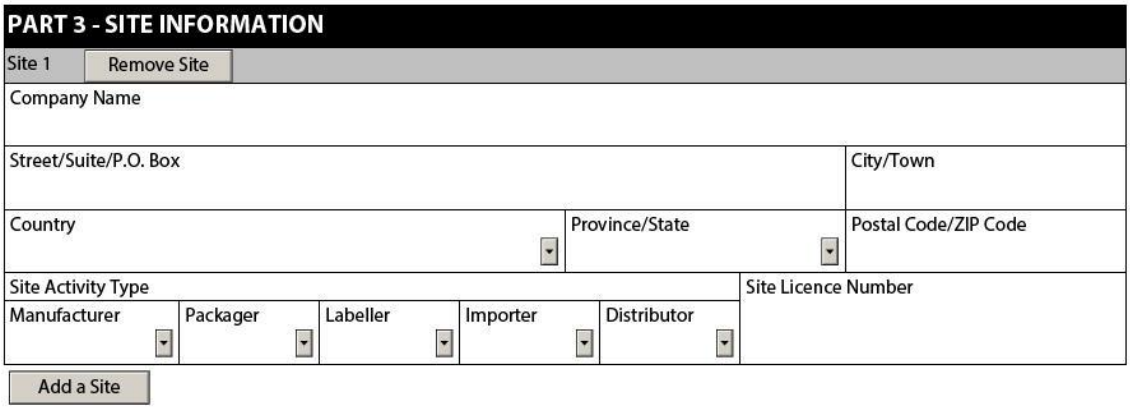
For more information on application requirements and information required to complete Part 2, please refer to the Product Licensing guidance document.

After the information has been entered, select the "***Continue***" button to validate the content of Part 2.

3.4 Site information (Part 3)

If this information is known/available at the time of applying for a product licence, the applicant should indicate all of the sites used in the manufacturing, distribution, labelling, packaging, and if applicable the importation of the NHP. The applicant should provide the name and address of each company.

Figure 9: Site information



For each company name and address provided, the associated activity/activities must also be indicated (such as manufacturer, packager, labeller, distributor, and/or importer.) If available, the site licence number assigned by the NHPD can also be provided.

Additional Sites blocks can be added by selecting the "***Add a Site***" button. Any of these blocks can be removed by clicking on the "***Remove Site***" button.

After the information has been entered, select the "***Continue***" button to validate the content of Part 3.

For more information on completing Part 3 of an ePLA Form, please refer to the Product Licensing guidance document.

3.5 Product information (Part 4)

3.5.1 Product information overview

Part 4 of the ePLA captures the product information required by the NHPD for its assessment. Part 4 of the ePLA is notably different from the original paper version of the PLA form. Some of the data fields have been reordered to account for dependencies on other fields. For example: since the Dosage Form is dependent on Route of Administration, the Route of Administration must be entered first. Additional fields have been added to align with the Natural Health Products Online System terminologies and standards (see Natural Health Products Online System Standard Terminology User Manual.)

TIP: Before beginning to capture information in Part 4, always make a point of saving the ePLA form with a unique name, closing it and then opening it again. This establishes a reference copy of the form that can be reused should you wish to no longer continue with information entered later (example: you decide to use a different monograph or to change the method of preparation).

The ePLA dynamically connects with the Natural Health Products Ingredients Database (NHPID) to obtain information related to standard terminologies for natural health products such as medicinal and non-medicinal ingredients, dosage forms, routes of administration, and units. The Natural Health Products Ingredients Database information on monographs is also accessed when applicable.

The selection of the type of application made in Part 2 determines the layout and behaviour of the ePLA in Part 4. Table 1 below shows the relative differences for each type of application.

Type(s) of application	NHPID information	Search by	Claims
Compendial (NHPD Monograph)	Single Ingredient and Product Monographs	Medicinal Ingredient Name	Free text (consistent with the chosen monograph)
Traditional Non-traditional	Medicinal Ingredients	Medicinal Ingredient Name	Free text
TPD Category IV / Labelling Standard	TPD cateogry IV Monographs and labelling standards	Medicinal Ingredient Name	Free text
NHPD Labelling Standard – Homeopathic Medicine Labelling Standard (HMLS)	Homeopathic Ingredients	Homeopathic Ingredient Name	Pre-determined list of four general claims
Homeopathic Medicine with Specific Claim	Homeopathic Ingredients	Homeopathic Ingredient Name	Free text
Homeopathic Medicine with Non-Specific Claim	Homeopathic Ingredients	Homeopathic Ingredient Name	Pre-determined list of four general claims

Table 1 – Types of ePLA applications

TIP: Adding information to the NHPID

For updates to or additions of **medicinal ingredients, non-medicinal ingredients** or **controlled vocabulary** (such as dosage form, units of measurement or NMI purposes), a separate form, the Natural Health Product Ingredients Database Issue Form must be used. Please consult the Natural Health Products Ingredients Database Issue Form User Manual for details on its use. For controlled vocabulary listings, please consult the NHPID's controlled vocabulary search. Completed Issue forms are to be sent to ingredient_support@hc-sc.gc.ca for review and inclusion in the NHPID.

3.5.2 Non-homeopathic applications

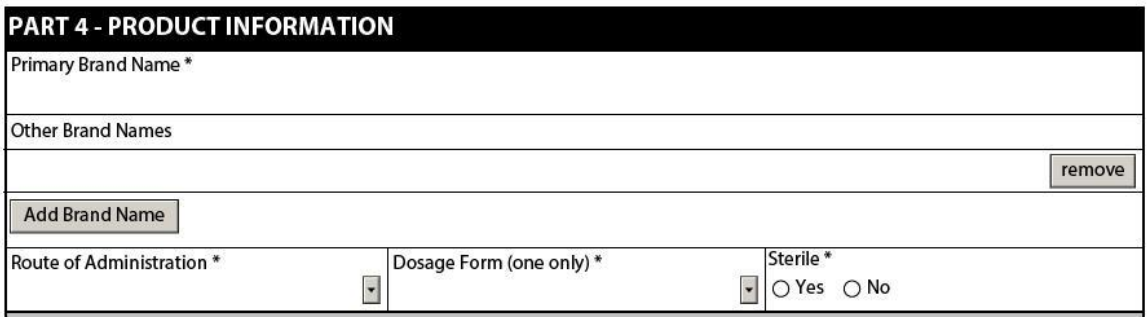
The following application types are non-homeopathic:

- Compendial
- Non-traditional;
- Traditional; and
- TPD Category IV/Labelling Standard.

Step 1: Heading

In the Heading of Part 4, as shown in Figure 10 below, general information about the product is required, including the primary brand name, other brand name(s), route of administration, dosage form, and sterility condition.

Figure 10: Heading for product information



Primary brand name: Free text. Can be entered either here or on the first page above Part 1 and will be updated in both locations.

Other brand name: Free text. To add more brand names, click on the "***Add Brand Name***" button and fill in the additional name. To remove an Other Brand Name, click on the "***remove***" button.

TIP: Enter one brand name per line

Sterile: When the application type is Compendial, the sterility condition is set to 'No' and the Sterile field is locked. For the other application types in this section, when the route of administration is chosen as 'Ophthalmic', the sterility condition is set to 'Yes' and the Sterile field is locked. For all other situations, the sterility condition is a choice of 'Yes' or 'No'.

Route of administration and dosage form: The route of administration is a pick list populated from the Natural Health Products Ingredients Database Routes of Administration Standard Terminology. An acceptable list of dosage forms is then provided based on the route of administration selected. Both the list of routes of administration

and dosage forms are derived from the ICH M5 data elements and standards. Please refer to the Natural Health Products Online System Standard Terminology Guide for further explanation.

TIP: Acceptable synonyms for dosage forms can be found in the NHPID; synonyms can be used on the marketed label.

Step 2: Block 'A' - Medicinal ingredients

Block 'A' captures information on the medicinal ingredient(s) associated with the product.

In the ePLA Form, ingredient profiles (sub-blocks) are added one-by-one, using the Natural Health Products Ingredients Database terminologies and standards. Please refer to Natural Health Product Online System Standard Terminology Guide for further information regarding the naming terminology. Ingredients are entered into the ePLA by searching the Natural Health Products Ingredients Database in the form.

To fill in the information for a medicinal ingredient, begin by selecting the "***Search Ingredient Database***" button to launch the Natural Health Products Ingredients Database search tool.

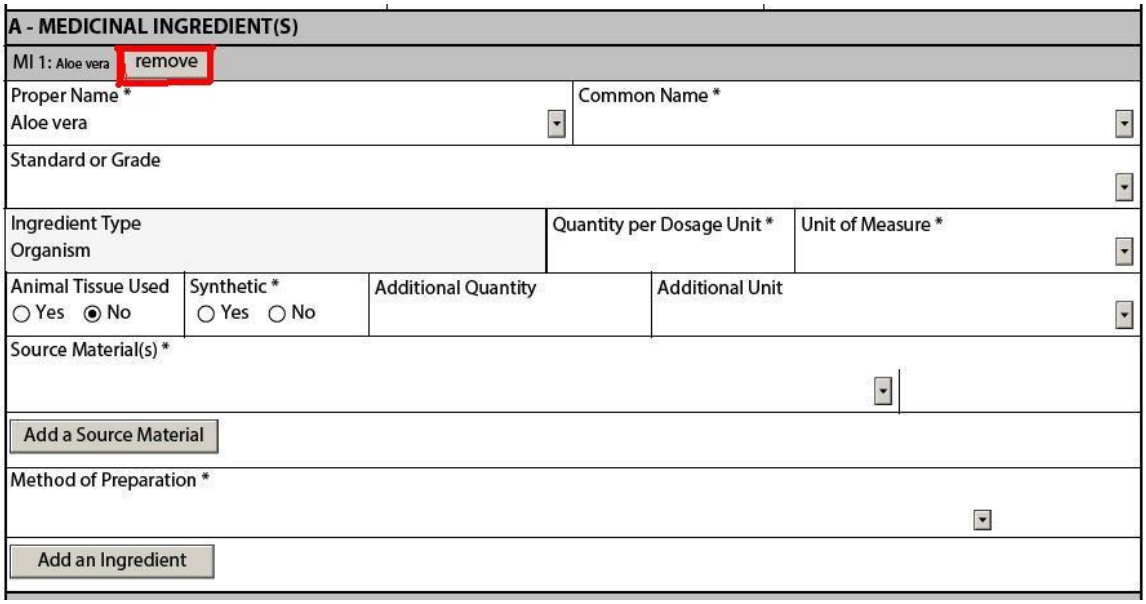
TIP: Before beginning to capture information in Part 4, research the ingredients of your product first in the NHPID to:

1. Ensure the ingredient already exists in the NHPID.
2. Know which ingredient to select when filling out the ePLA as some ingredients may **appear** to be the same but have differences in constituents, extract information, methods of preparation, etc…

After selecting an ingredient, some fields will be automatically pre-populated based on information found in the Natural Health Products Ingredients Database. If the required ingredient information cannot be found in the Natural Health Products Ingredients Database, the applicant can request that the information be added formally through the Natural Health Products Ingredients Database Issue process (see Natural Health Products Ingredients Database Issue Form User Manual.)

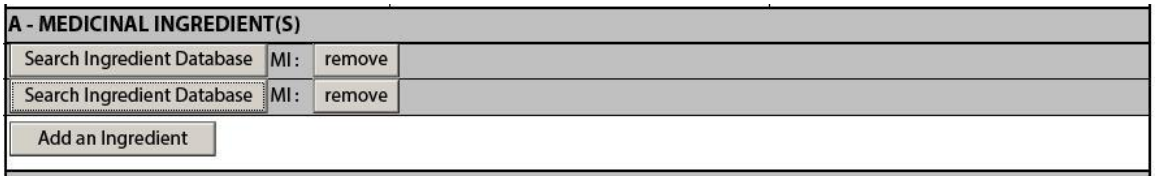
Removing ingredients: Ingredients can be removed from the application by selecting the "***remove***" button as shown below.

Figure 11: Remove an existing medicinal ingredient



Adding ingredients: The ePLA shows one empty medicinal ingredient sub-block to start because at least one medicinal ingredient is required to successfully finalize the form. More ingredients can be added to the application by selecting the "***Add an Ingredient***" button. This will create a new empty ingredient sub-block.

Figure 12: New (empty) ingredient



Searching the ingredients database

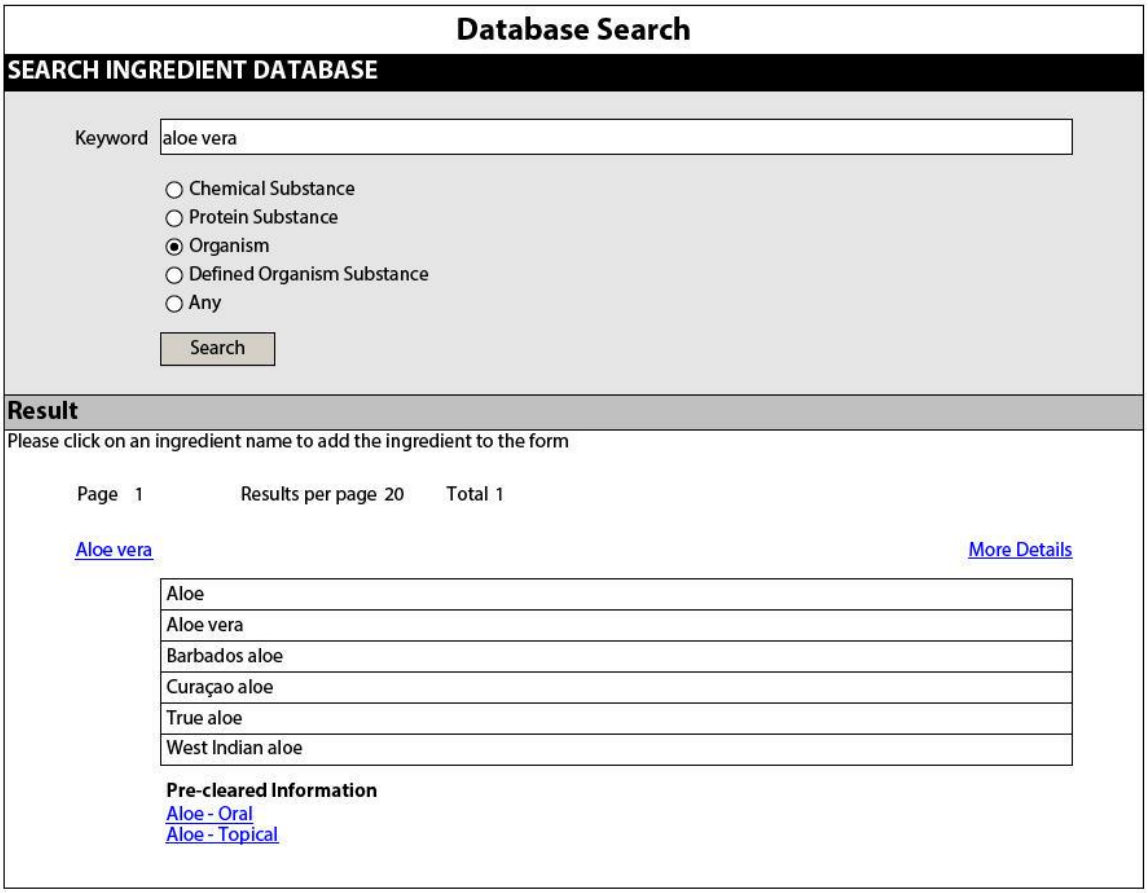
The ingredient search tool is designed to search and retrieve data from the Natural Health Products Ingredients Database. It can be used for searching both medicinal and non-medicinal ingredients. The following fields are searched:

- NHPID name;
- Proper names;
- Common names;
- Synonym;
- Taxonomical synonyms (Taxa); and
- Chemical Abstracts Service(CAS) numbers

Selecting the "***Search Ingredient Database***" button invokes the search tool. To search for an ingredient, enter a keyword and click Search. A message indicating the number of

results will appear before the search result page is displayed. When an ingredient has an associated monograph or abbreviated labelling standard, this is indicated in the search result as pre-cleared information. (See Figure 13 for an example of a successful ingredient search result).

Figure 13: Example of a successful ingredient search result



Selecting a filter: The search engine has a default of all ingredient types; however, if you know the type of the ingredient, you may check the type accordingly. For detailed definitions of the ingredient types, please refer to the Natural Health Products Online System Standard Terminology User Manual. Check "Any" to search all types.

Inputting a keyword: Input simple keywords only. Operators such as "and" and "or" are not applied and may cause the search to be unsuccessful. All information that is entered will be treated as a 'single word'.

Using wildcards: Wildcards are acceptable. Use quotation marks "" to search for an exact match (spelling must also be exact). Use '*' or '%' for zero or more continuous characters and '_' for a single character. Example: if you launch a search with 'green*flavour ' or 'green%flavour ', the results will include 'Green Tea Flavour '. For

more details, please review the Natural Health Products Ingredients Database Web Application Guide.

Conducting a search: Select the ***Search*** button to start searching. Searching can also be triggered by depressing the <Enter> key.

For applications of type Non-traditional, Traditional and TPD Category IV/Labelling Standard, the entire set of non-homeopathic medicinal ingredients of the NHPID is searched. For applications of type Compendial, only those ingredients present in non-homeopathic NHPD single ingredient and product monographs are searched. Search results are presented in alphabetical order of NHPID name.

Getting detailed information of an entry: Selecting the hyperlink " More Details" on the right shows the detailed information of the ingredient found in the NHPID through the Web browser.

Selecting an entry: Selecting the hyperlinked ingredient name on the left fills the related fields in the ePLA.

When a search fails: The failure of a search does not always mean the specified ingredient is missing from the database. The following situation may contribute to a failed search:

- Spelling errors;
- Improperly using wildcards; and / or
- Using a spelling variant that is different from the spelling used in the database.

  This may happen in cases that there are different spellings of a term among American, Canadian, and British English, and in cases where there is more than one spelling for a Latin binominal name.

The conclusion of "no ingredients found" can only be reached after performing a sufficient and proper search. An example of a search result is shown above in Figure 13: Example of a Successful Ingredient Search Result . If you are experiencing difficulty finding ingredients through the search function of the ePLA, it is best to fully explore the ingredient using the NHPID.

When a search fails under the Compendial application type, it likely means that the ingredient does not appear in a non-homeopathic NHPD monograph. An application type other than Compendial must be considered.

TIP: Please note that if any name or term cannot be found from the search tool or from pick lists, the user will need to fill out an NHPID Issue form and send it to the NHPD (see Natural Health Products Ingredients Database Issue Form Guide) to request that the missing information be added to the database.

Presentation of medicinal ingredients

Depending on the type of ingredient selected, the layout and required fields of Block 'A' will vary. In general, the following components are in Block 'A':

Figure 14: Ingredient names

However, since the data for different ingredient types varies, the completed fields of Block 'A' capture different information to reflect the requirements of each specific ingredient.

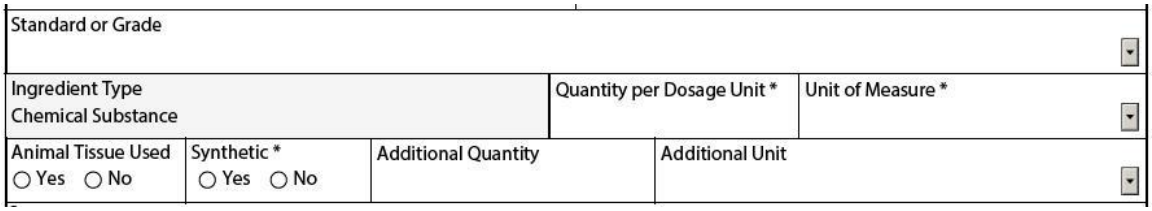
Ingredient names

Proper name: Ingredient's proper name. Select one from the pick list. All proper names are pre-populated from the Natural Health Products Ingredients Database and are based on the *Natural Health Products Regulations*.

Common name: Common name of the ingredient. Select one from the pick list. All common names in the pick list are pre-populated from the Natural Health Products Ingredients Database and are derived from authorized references.

Basic information
There are 8 fields in this part as shown in the figure below.

Figure 15: Basic information of the ingredient



Standard or grade: If the ingredient conforms to a particular standard or grade (such as United States Pharmacopoeia, British Pharmacopoeia, etc.), it can be stated here. The pick list of pharmacopoeia presents pharmacopoeial grades acceptable to the NHPD. The Standard or Grade is not a required field.

Ingredient type: One of 4 ingredient types - chemical substance, protein substance, organism, and defined organism substance – is pre-populated based on the ingredient selected.

Quantity per dosage unit: Amount of the ingredient used in the product formulation per dosage unit. This must be a number only.

Unit of measure: Unit for the quantity. This pick list is populated based on the Natural Health Products Online System Standard Terminology User Manual. The most popular units – Grams, Micrograms, Milligrams, Millilitres and Percent – are shown first followed by the other units in alphabetical order

Animal tissue: This field is pre-populated based on simple rules but its content should always be checked. If the ingredient is derived from an animal tissue, check "Yes" and fill out the Animal Tissue Form that will be appended to the end of this form (see Animal Tissue Form – section 3.7); otherwise check "No".

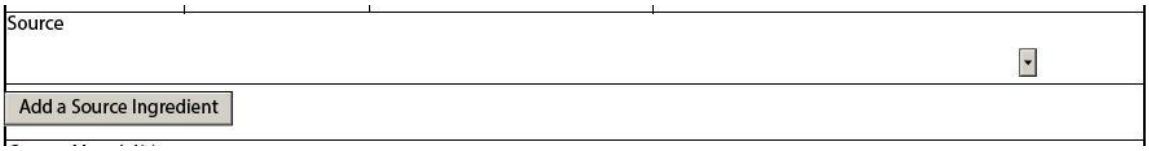
Synthetic: Check "Yes or no" as appropriate for the ingredient.

Additional quantity: Amount of the ingredient using other units. This must be a number only.

Additional unit: Unit for the additional quantity. This pick list contains a subset of valid additional units.

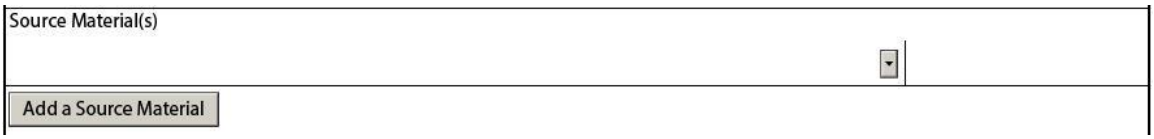
Source ingredients: From the pick list select the ingredient source from which the ingredient was isolated. (See Figure .). To capture more than one source, click the "***Add a Source Ingredient***" button. Source materials are a combination of an organism and an organism part. For ingredients having both Source ingredients and Source Materials, there must be a selection from at least one of the two fields.

Figure 16: Source ingredient



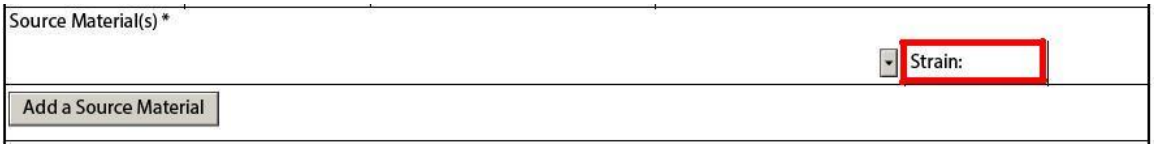
Source material: Select the Source Material from the pick list provided, if applicable. (see Figure 17.) If there are many source materials included in the formulation, click the "***Add a Source Material*** " button. When an ingredient is derived from an organism group, the Source Material drop-down will include not only the group, but also the group components. For example, for ingredient 'Oyster Shell', the source material will consist of not only the 'Oyster' group and the relevant 'Shell' part, but also the individual genus/species associated with this group along with the relevant part. For ingredients having both Source ingredients and Source Materials, there must be a selection from at least one of the two fields.

Figure 17: Source material



For probiotics and bacteria, an extra field entitled 'Strain' is provided to enter the bacterial strain number. This field is mandatory for probiotics and non-mandatory for bacteria.

Figure 18: Source material and strain



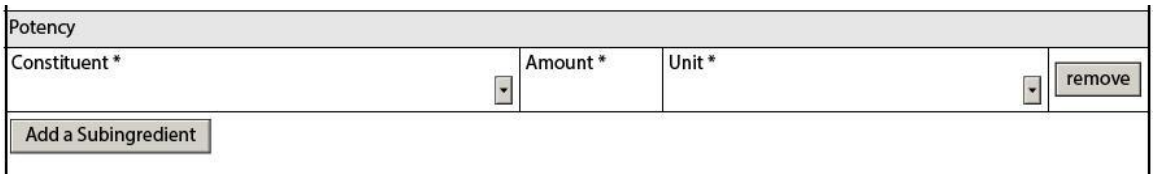
Method(s) of preparation: The preparation method used for the ingredient is required only for organism and organism substance types. A long pick list of methods of preparation is populated for ingredients of Organism type and a short list for ingredients of Defined Organism Substance type. Detailed information on the NHPD methods of preparations can be found in the Natural Health Products Online System Standard Terminology User Manual.

Figure 19: Methods of preparation

Potency: The concentration of the active or marker constituents of an ingredient is required only for ingredients of Defined Organism Substance type when the method of preparation is standardized (see the Natural Health Products Online System Standard Terminology User Manual.) Three fields are required for potency: constituent (name), quantity, and unit (see Figure 20). The NHPD has been capturing acceptable constituent data for natural substances. If constituent data is available for a particular organism part, a pick list of constituents will be pre-populated. In the case where the constituent cannot be found in the list or no populated list is available, then the applicant can request that the information be added formally through the Natural Health Products Ingredients Database Issue process (see the Natural Health Products Ingredients Database Issue Form User Manual – see *Adding Information to NHPID* above).

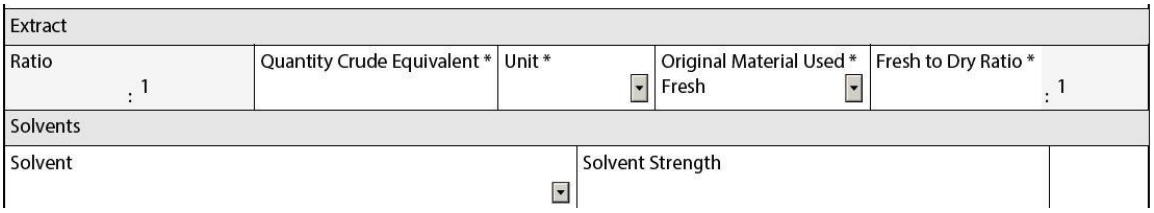
To capture more constituents, click on the "***Add a Subingredient***" button.

Figure 20: Potency



Extracts and solvents: The detailed information about processing organism ingredients is required only for organism-type ingredients (see Figure 21). The required fields are determined according to the method of preparation selected. More detailed information can be found in Section 4.1 - Approved Organism Substance Preparation Name of the Natural Health Products Online System Standard Terminology User Manual.

Figure 21: Extracts and solvents



Ratio: Ratio of the quantity (usually weight) of raw material used to the quantity (weight or volume) of final preparation. The ePLA will automatically calculate the ratio, which is not editable, when the Quantity per Dosage Unit and the Quantity Crude Equivalent are both provided. More detailed information can be found in the Natural Health Products Online System Standard Terminology User Manual.

Quantity crude equivalent and unit: The quantity of crude material equivalent to final preparation and the unit for the quantity.

Original material used: It must be indicated whether the original material used is dry or fresh. If "Fresh" is selected, a mandatory field entitled "Fresh to Dry Ratio" appears.

Solvent: Solvent used for the preparation must be chosen from the pick list provided. To capture more solvents, click on the "***Add a Solvent***" button.

TIP: If the solvent appears in the finished product, it must also be indicated in the Non-medicinal ingredient section of the ePLA.

Solvent strength: Numeric value (%) is required. More detailed information can be found in the Natural Health Products Online System Standard Terminology User Manual.

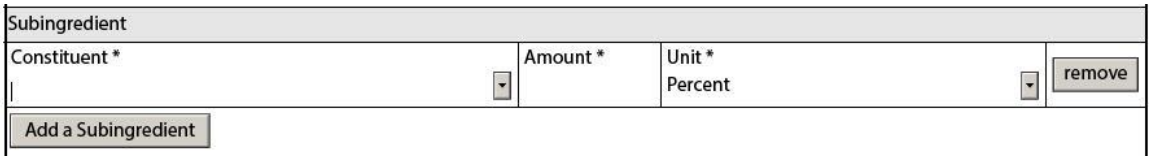
Subingredient: When an ingredient is defined with subingredients in the NHPID (for example, Calcium phosphate monobasic has Calcium and Phosphorus as sub-ingredients), the Subingredient component is displayed as shown in Figure 22. To capture more subingredients, click on the "***Add a Sub-ingredient***" button.

Constituent: Choose the constituent name from the pick list provided.

Amount: A numeric value is required.

Unit: The pick list will include the Unit of Measure chosen for the ingredient plus "Percent"

Figure 22: Subingredient

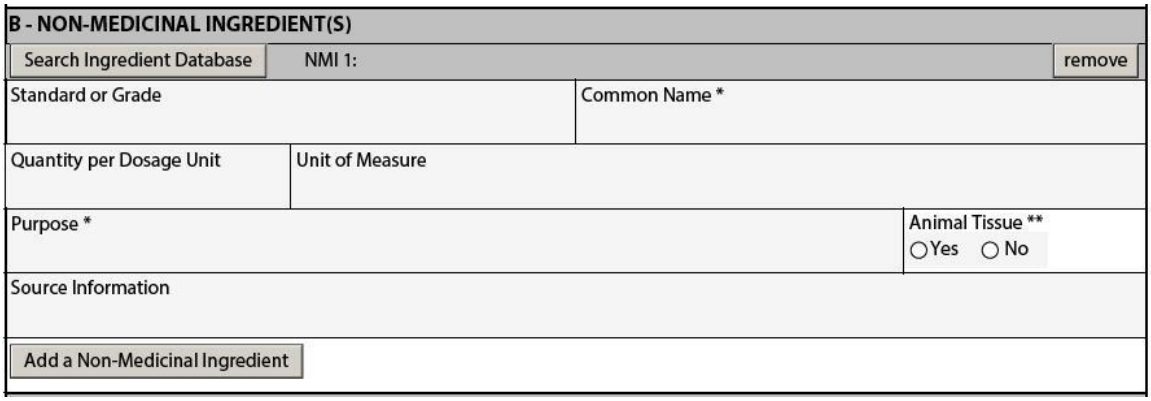


Step 3: Block 'B' - Non-medicinal ingredients

Like medicinal ingredients, non-medicinal ingredients are selected by searching the Natural Health Products Ingredients Database. For all application types, the entire set of non-medicinal ingredients of the NHPID is searched.

When selecting ingredients, some fields will be automatically pre-populated based on the Natural Health Products Ingredients Database ingredient naming standard.

Figure 23: Non-medicinal ingredient information



Standard or grade: Pharmacopoeia or other grade or standard with which the ingredient will comply. The pick list of standards and grades represents pharmacopoeial grades acceptable to the NHPD. This field is not required and only needs to be completed as required or if applicable to the ingredient.

Common name: Select the name for the ingredient from the pick list of common names for the chosen non-medicinal ingredient.

Purpose: Select a purpose from the pick list of valid non-medicinal ingredient purposes for this ingredient found in the NHPID. If "Flavour enhancer" is a valid purpose in the NHPID, the drop-down will contain both "Flavour enhancer – Artificial" and "Flavour

enhancer – Natural". Please see the NHPID for the controlled list of acceptable non-medicinal ingredient purposes. If the required purpose is not found, complete an Ingredient Issue Form to add the desired purpose to the ingredient (see *Adding Information to the NHPID* above).

Quantity per dosage unit: If applicable, enter the amount of the ingredient used in the product formulation. This must be a number only and is an optional field.

Unit of measure: Unit for the quantity. This pick list is populated based on the Natural Health Products Online System Standard Terminology User Manual.

Animal tissue: This field is pre-populated based on simple rules but its content should always be checked. If source material is non-human animal, check "Yes" and fill out the Animal Tissue Form at the end of this form; otherwise check "No".

Source information: If applicable, describe the origin of the non-medicinal ingredient. This field is optional.

Step 4: Block 'C' - Ingredient(s) used in processing

As shown below in Figure 24, this question relates to whether or not animal tissue was used directly or indirectly in the processing of the product but not present in the finished product. If yes, check "Yes" and fill out the Animal Tissue Form at the end of this form; otherwise check "No".

Figure 24: Ingredient(s) used in processing

C - INGREDIENT(S) USED IN PROCESSING		
Was animal tissue used in the processing of this **product**, although not present in the final product?**	○ Yes	○ No

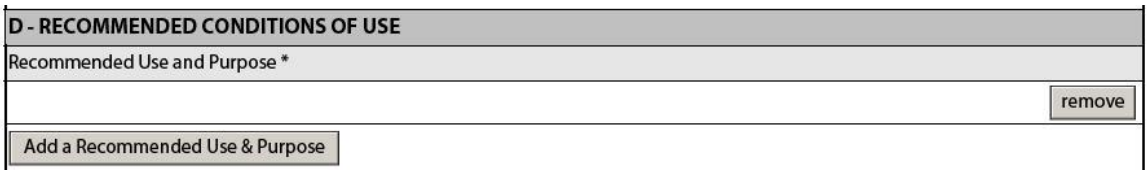
Step 5: Block 'D' - Recommended conditions of use

The Recommended Conditions of Use block captures the following information:

- Recommended use or purpose;
- Recommended dosage, including directions of use for each sub-population group;
- Duration statement(s); and
- Risk information.

Recommended use(s) or purpose: Provide at least one statement in free form text in the area shown below in Figure 25. At least one use or purpose statement must be indicated. If using more than one use/purpose, please indicate these individually, i.e. on separate lines. To add another statement, click on the "***Add a Statement***" button.

Figure 25: Recommended use(s) or purpose

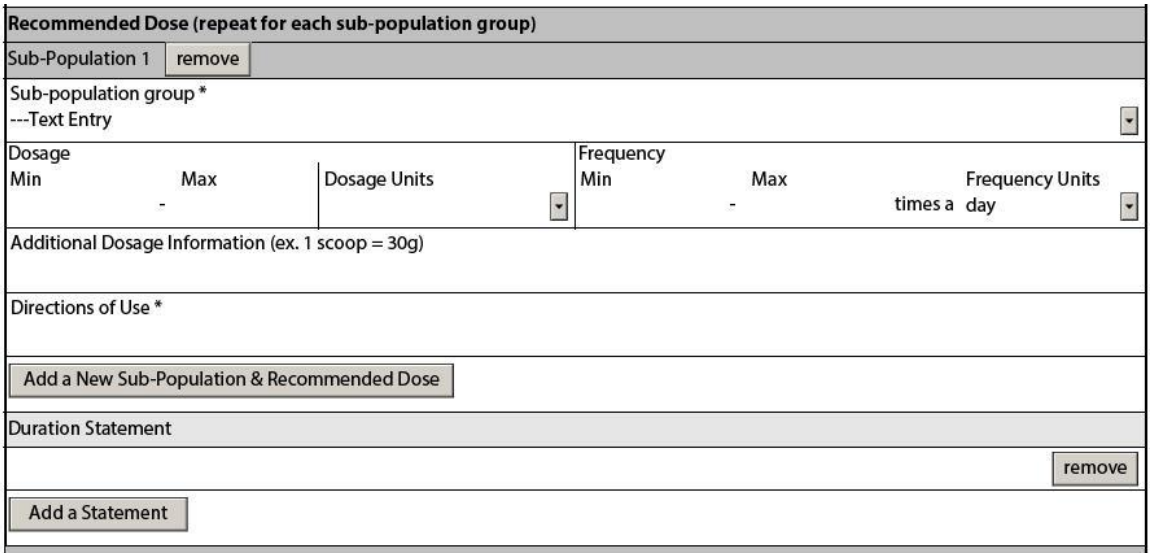


TIP: In certain instances, you may find that the text of your Recommended Use(s) or Purpose exceeds the limit (shown by a plus sign - + - at the end) Should that happen, it is suggested that you add another statement line in order to continue with the text. This ensures that all text will be clear and visible should you intend to print the ePLA at a later time.

Recommended dose

Recommended Dose is required for all products. One set of information is captured for each sub-population group as shown below.

Figure 26: Recommended dose



Sub-population group: Either select one of the provided sub-population groups or enter your own subpopulation, including age range, by replacing ***"---Text Entry"***. If more than one sub-population group is required, click on the "***Add a New Sub-Population & Recommended Dose***" button to generate a new recommended dose block.

Dosage: Required for oral products and other discrete dosage forms. Min and Max values must be numeric. Dosage Units is chosen from a pick list based on dosage form chosen.

Frequency: Min and Max values must be numeric. Frequency Units default to "day".

TIP: If dose is 1 capsule 1x/day, enter '1' in the min and max fields for dosage and frequency.

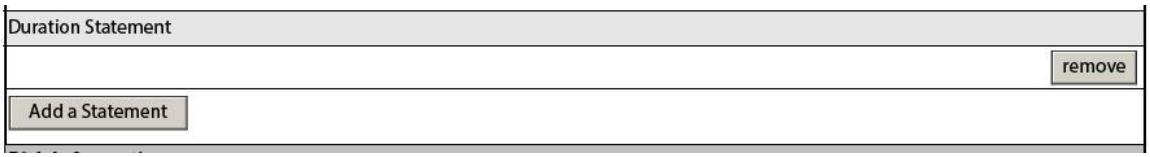
Additional dosage information: Optional free text.

Directions of use: Optional free text.

Duration statement:

Optional free text. If additional statements are desired, click on the "***Add a Statement***" button.

Figure 27: Duration statement



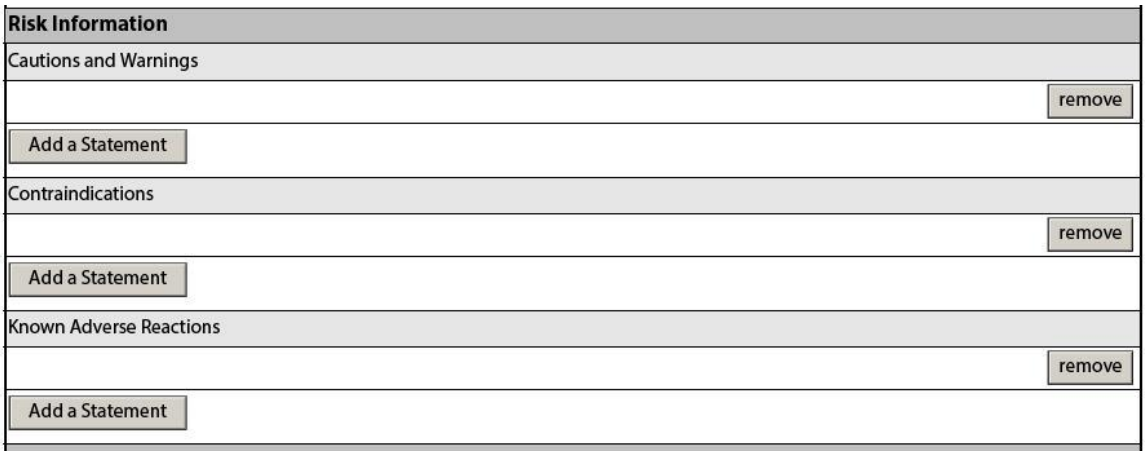
Risk information:

As shown in Figure 28 below, risk information consists of:

- Cautions and warnings;
- Contraindications; and
- Known adverse reactions.

All are optional free text. If additional statements are desired, click on the "***Add a Statement***" button.

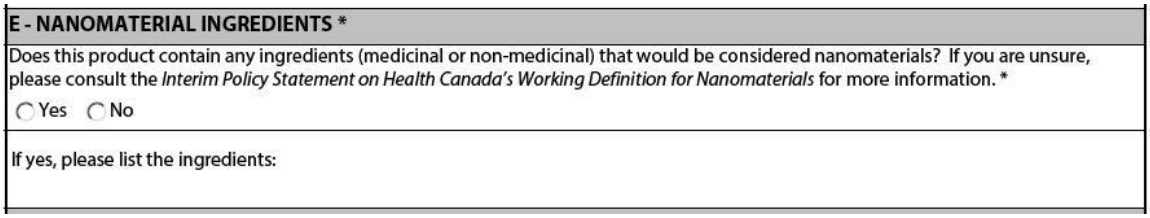
Figure 28: Risk information



Step 6: Block 'E' – Nanomaterial ingredients

A "yes" or "no" response is required to the nanomaterial ingredients question as shown below in Figure 29. If the answer is "yes", the list of nanomaterial ingredients is required. Please note that nanomaterials are not permitted in the Compendial application stream.

Figure 29: Nanomaterial ingredients information



Step 7: Block 'F' – Animal Tissue Form

Block 'F' contains a "***Go to the Animal Tissue Form***" button that will take you to the first animal tissue form. All animal tissue forms must be completed before you can validate the form.

Step 8: Validate part 4

After the information has been entered, click on the "***Continue***" button to validate the content of Part 4.

For more information on meeting requirements in an ePLA, refer to the Product Licensing guidance document.

3.5.3 Homeopathic applications

Three types of homeopathic applications (NHPD Labelling Standard - Homeopathic Medicine Labelling Standard (HMLS), Homeopathic Medicine with Specific Claim, and Homeopathic Medicine with Non-Specific Claim) can be selected in Part 2 from the field entitled 'Application Type'. When one of those application types is selected, Part 4 of the form takes on a look that's different from the other application types because homeopathic applications have different medicinal ingredient information requirements. All homeopathic applications have attestation statements that must be accepted for successful validation. The following figures distinguish the attestation statements for the three types:

Figure 30: Homeopathic Medicine Labelling Standard (HMLS) attestation

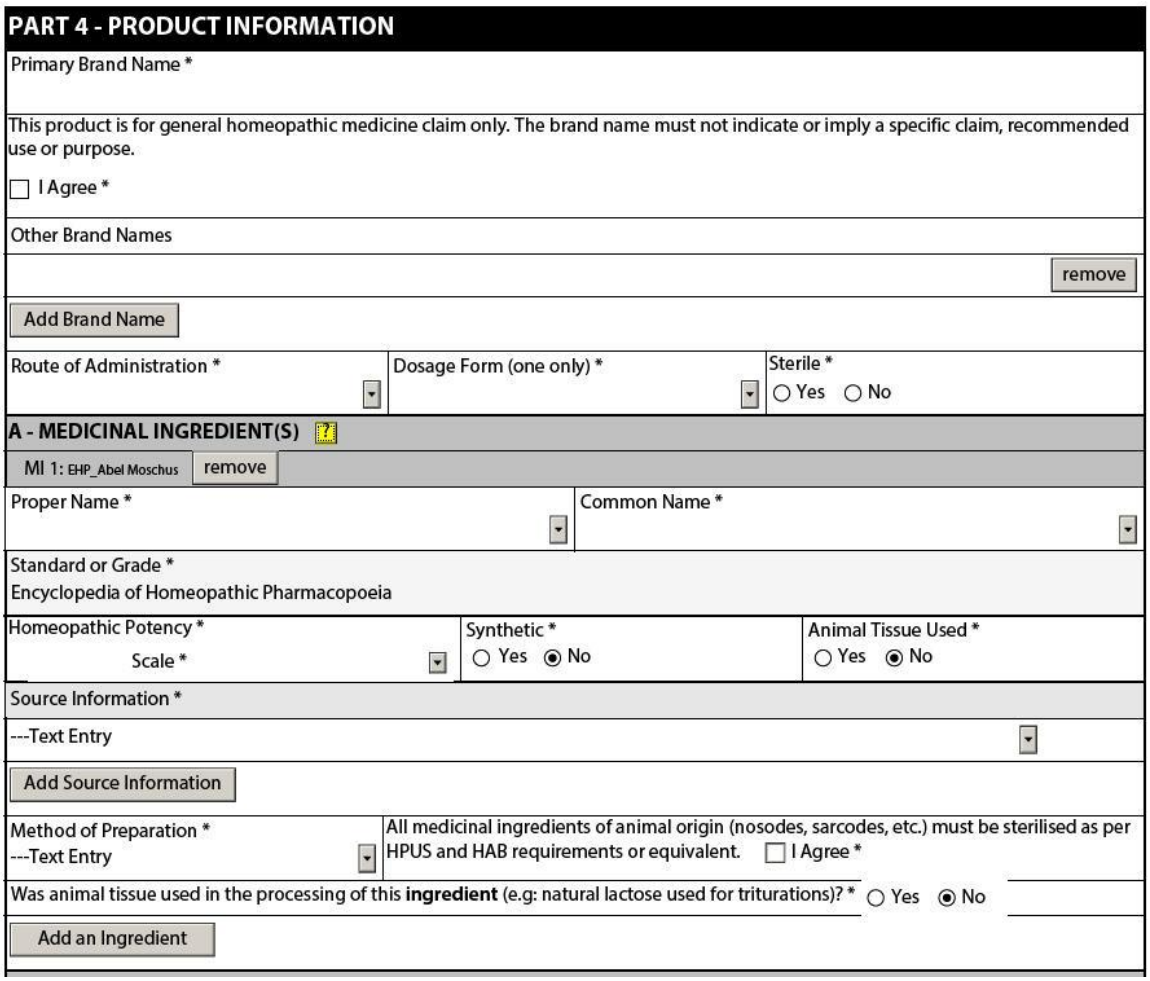


Figure 31: Homeopathic specific attestations

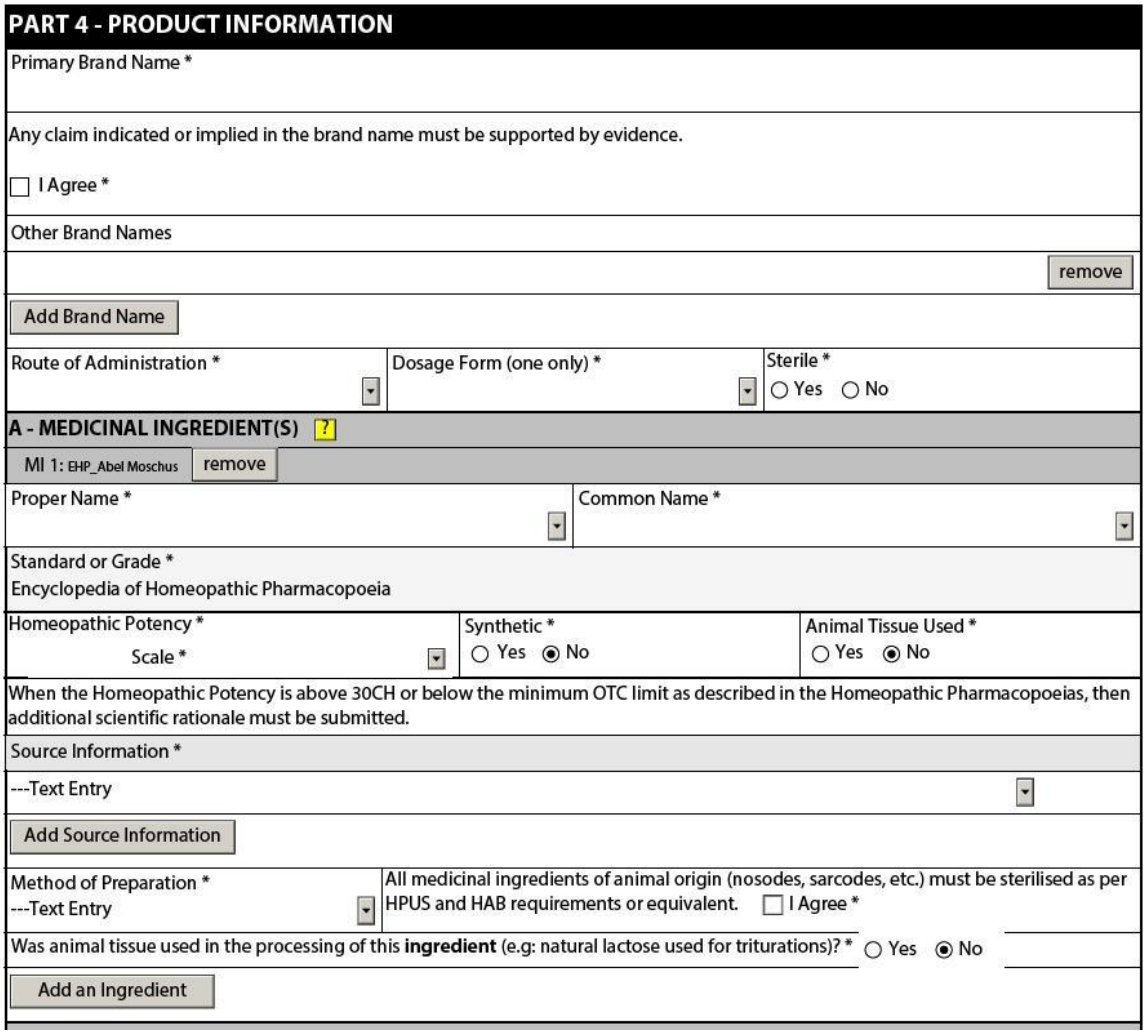
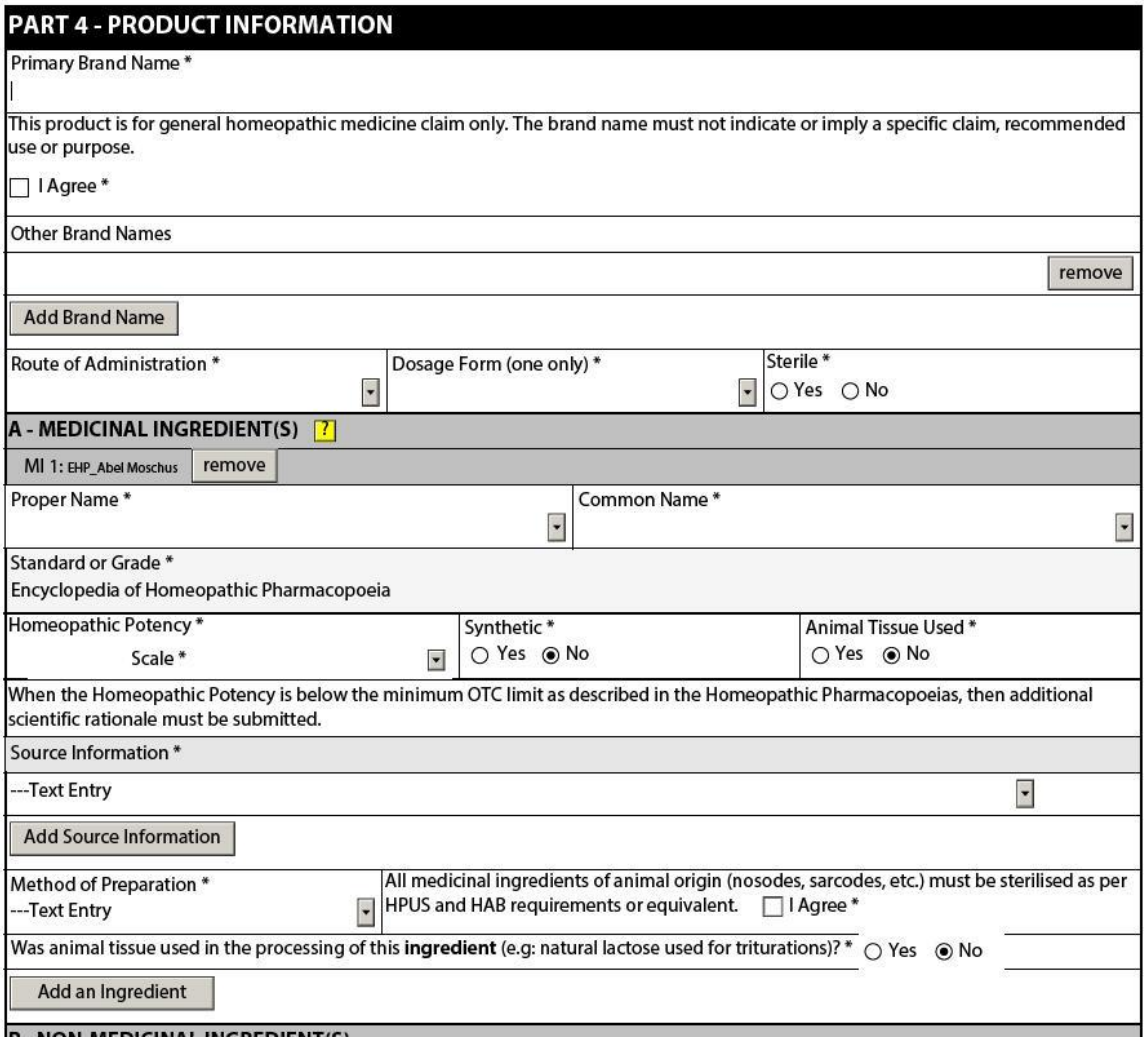


Figure 32: Homeopathic non-specific attestations



As with other non-compendial applications, a homeopathic application search is performed on the ingredients. However, in this instance, the search is solely on homeopathic ingredients seen in the following five references: Homeopathic Pharmacopoeia of the United States (HPUS), Encyclopedia of Homeopathic Pharmacopoeia (EHP), German Homeopathic Pharmacopoeia (HAB), European Pharmacopoeia (PhEur), and Pharmacopée française (PhF).

Selecting the "***Search Ingredient Database***" button invokes the search tool.

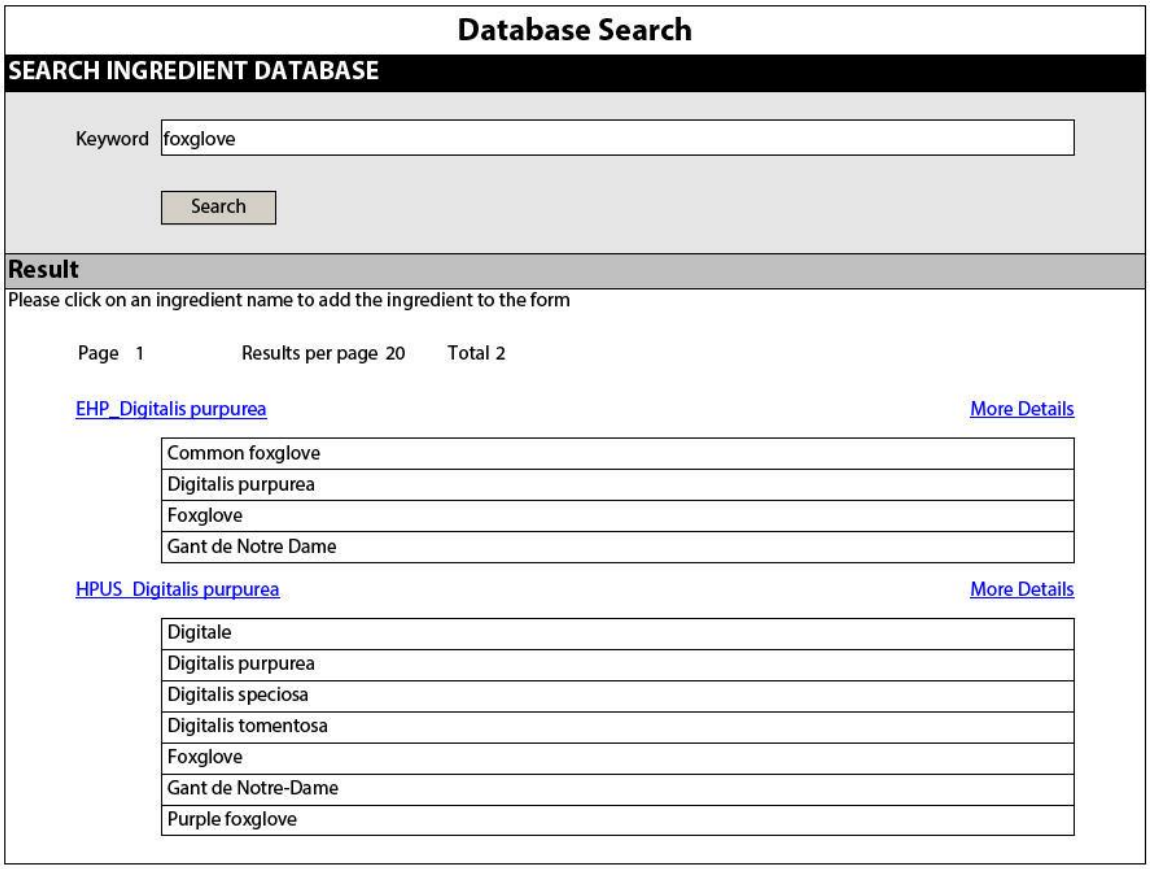
Inputting a keyword: Input simple keywords only. Operators such as "and" and "or" are not applied and may cause the search to be unsuccessful. All information that is entered will be treated as a 'single word'.

Using wildcards: Wildcards are acceptable. Use '*' or '%' for zero or more continuous characters and '_' for a single character. Example: if you launch a search with 'digi*urea'

or 'digi%urea' in one of the three homeopathic application types, the results will consist of four ingredients based on 'Digitalis purpurea'.

Conducting a search: Select the "***Search***" button to start searching. Searching can also be triggered by depressing the <Enter> key. A message indicating the number of results will appear before the search result page is displayed.

Figure 33: Example of a homeopathic ingredient search result



Results are displayed in alphabetical order of NHPID name.

Selecting an entry: Selecting the hyperlinked ingredient name on the left fills the related fields in the main form.

When a search fails: The failure of a search does not always mean the specified ingredient is missing from the database. The following situation may contribute to a failed search:

- Spelling errors including the presence or absence of accents;
- Improperly using wildcards; and / or
- Using a spelling variant that is different from the spelling used in the database. This may happen in cases that there are different spellings of a term among

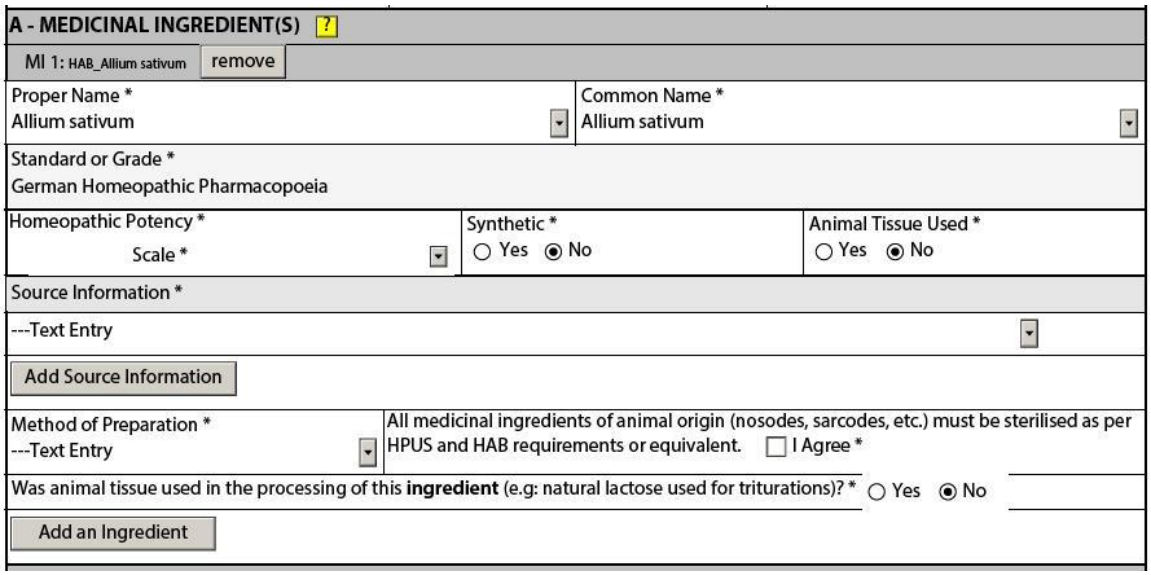
American, Canadian, and British English, and in cases where there is more than one spelling for a Latin binominal name.

The conclusion of "no ingredients found" can only be reached after performing a sufficient and proper search.

After finding an ingredient, as seen in Figure 34 below, the following fields will be pre-filled from the Ingredients Database: Standard or Grade, Proper Name, Common Name, Synthetic, Animal Tissue Used, Source Information, Method of preparation and whether animal tissue was used in processing the ingredient. All textual information will appear in the original language of the pharmacopoeia, meaning English for all pharmacopoeias, except for ingredients coming from the Pharmacopée française where the information is in French only. This is the only situation where ingredient information may not be consistent with the language chosen for the ePLA.

The form allows for substitution of **Source Information** and **Method of Preparation** information pre-filled from the database by replacing the ***'---Text Entry'*** selection with freeform text.

Figure 34: Successful ingredient selection for homeopathic application



A brief explanation is provided for fields that are unique to homeopathic applications.

Homeopathic potency: The dilution or potency applied in the product in homeopathic units only. The applicant is free to select from the scale values provided or to enter another value.

Sterilisation of ingredient from animal origin: Must check 'I agree' box to indicate that medicinal ingredients of animal origin such as nosodes, sarcodes and so on have been sterilised as per pharmacopoeial requirements.

Animal tissue in processing ingredient: Must indicate whether animal tissue was used in processing the ingredient, such as using natural lactose for triturations.

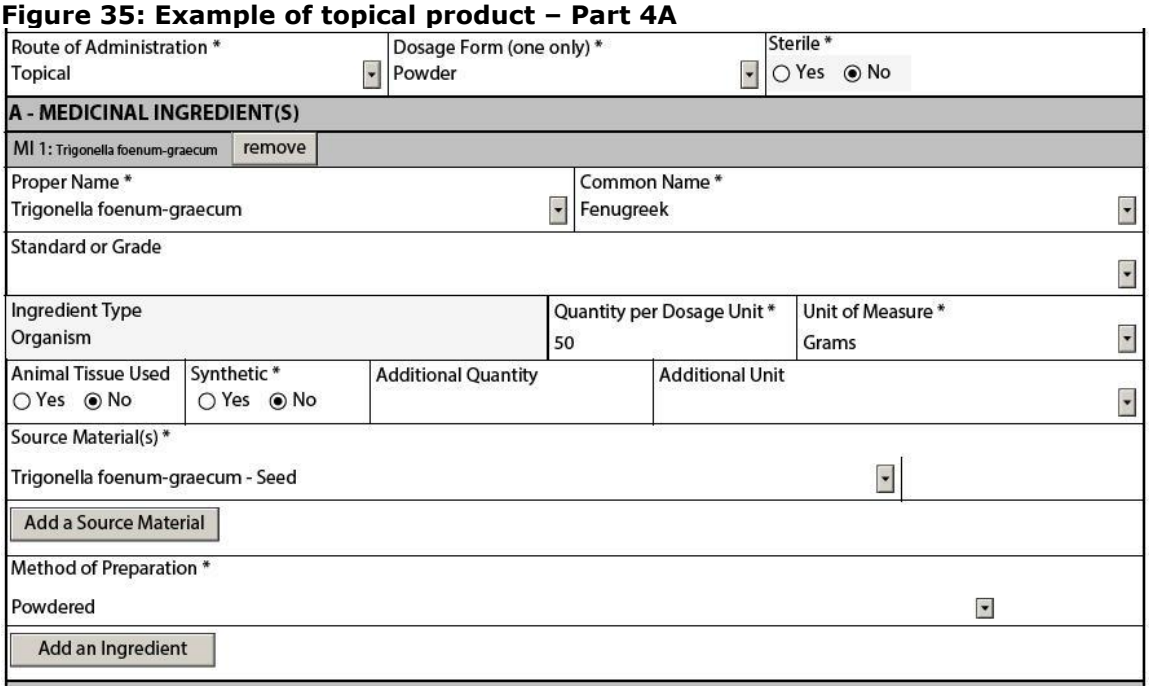
During form validation, various rules associated with the three homeopathic application types and related to homeopathic potency will have to be met. This is in addition to ensuring that all mandatory fields have been filled. Label text generation in Part 5 is no different for the homeopathic application types.

3.5.4 Applications with non-oral routes of administration

Filling in an ePLA with a route of administration other than 'Oral' can sometimes prove challenging. When either 'Buccal' or 'Topical' is chosen as the route of administration, the form validation will behave differently as the dosage and frequency fields of the Recommended Dose section will no longer be mandatory as long as a directions for use is entered.

An example from a Compendial application type is given to illustrate. A topical Fenugreek cream with 50 grams of powdered seed and which meets the Fenugreek monograph will appear in the ePLA as shown below.

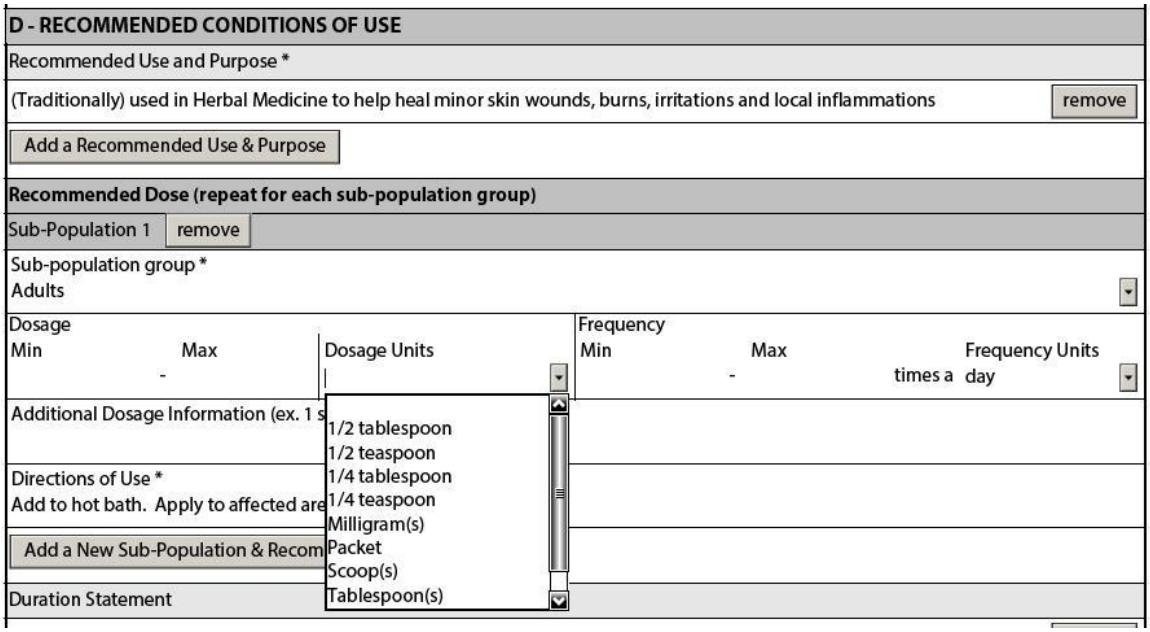
Figure 35: Example of topical product – Part 4A



Similarly, if the product is an extract, a method of preparation of 'Extract dry' is selected and the quantity of 50 grams is entered in the Quantity Crude Equivalent field. Based on the extract ratio, the appropriate quantity is input in the quantity per dosage unit fields.

In the Recommended Dose section, the user will have the option to indicate the appropriate dosage units. If the 50 grams of fenugreek were per 'amount' of cream, the Dosage Unit section would have to indicate it as such. Or the user can choose to leave the dosage and frequency sections empty.

Figure 36: Example of a topical product – Part 4D



3.6 Label text (Part 5)

3.6.1 Label text editor

As well as supporting the ability to submit label text, Part 5 of the ePLA form provides a Label Text Editor tool to generate regulatory label text directly from the contents of the ePLA.

The Label Text Editor tool provides the opportunity to review and possibly edit the generated label text or, alternatively, indicate that the label text will be provided separately along with the ePLA form. If the generated label text approach is chosen, the text must be successfully validated before the ePLA form can be finalized.

The initial version of the generated label text is assembled from the information entered in the ePLA. The applicant is then able to review this initial version and to provide clarifying and additional information as appropriate. The content is organized by panel as per Section 93 of the *Natural Health Products Regulations* and published in the Labelling Guidance Document. At any time, the applicant can select the "***View***" button to view the finished results. Once the finished results are satisfactory, the applicant validates the label text by selecting the "***Validate***" button. Any aspects that are inconsistent with the

Natural Health Products Regulations and labelling guidance are highlighted for correction. When the label text validates cleanly, the applicant can then proceed to finalize the ePLA.

3.6.2 Edit and validate label text

Select the "***Edit Label Text***" button to display the Label Text Editor. As per the labelling guidance, there are five sections in the Label Text Editor:

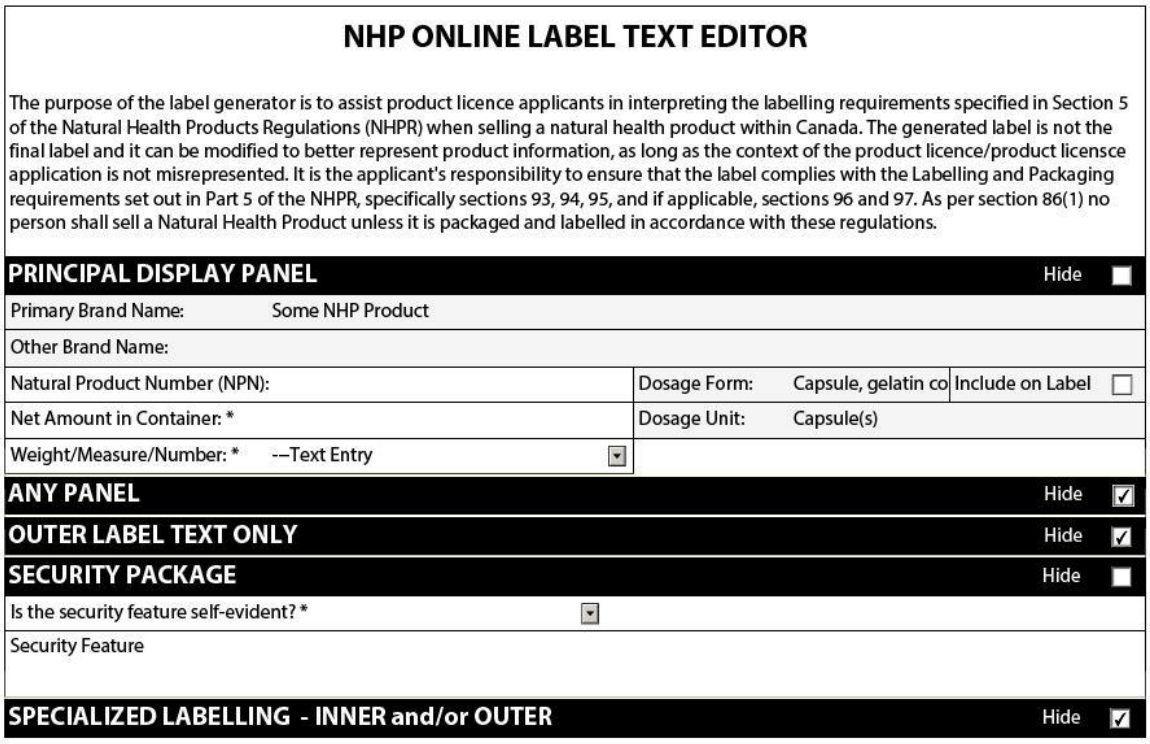
1. Principal Display Panel;
2. Any Panel;
3. Outer Label Text Only;
4. Security Package; and
5. Specialized Labelling - Inner and/or Outer.

Each section contains one or more subsections. A section or subsection can be displayed or hidden by selecting in the corresponding "***Hide***" checkbox.

The field values displayed in the sections/subsections are from Parts 1, 3, and 4 of the ePLA. Mandatory fields are identified with an asterisk (*). Some field values may be replaced for label text purposes by entering a new value in the corresponding "Replace with a statement to the effect of:" field, while other field values can be included on (or removed from) the label text by selecting in the corresponding "***Include on Label*** "checkbox.

Front panel: In the Front Panel section, shown in Figure 37: Front Panel Section below, the Net Amount in container field is a mandatory field that can be modified by the user. By selecting 'Text Entry' in the weight/measure/number drop-down, the users can input their own container units.

Figure 37: Front panel section



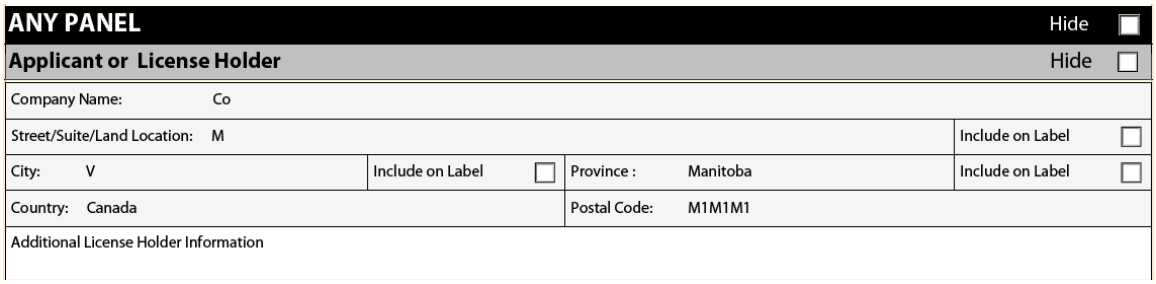
TIP: The weight/measure/number section can be entered as free text by applicants to show multiple container amounts for their products.

Any panel: The Any Panel section contains five subsections:

- Applicant or Licence Holder
- A - Medicinal Ingredient;
- D - Recommended Conditions of Use;
- Recommended Dose; and
- Provided by Applicant.

Certain fields within the Product Licence Holder subsection, as in Figure 38: Product License Holder Subsection below can be visible for label text purposes.

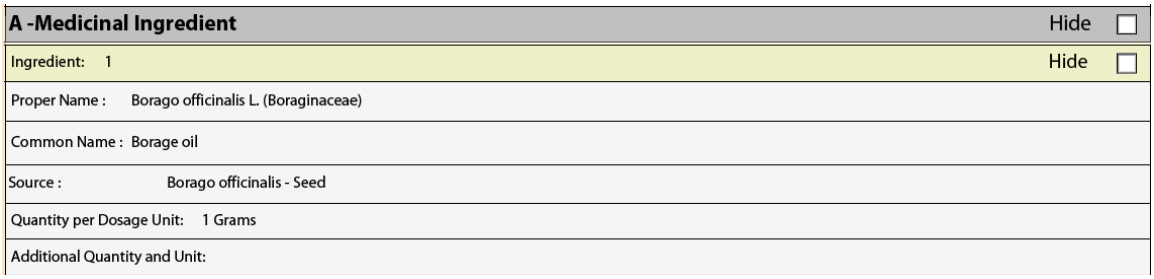
Figure 38: Product license holder subsection



ANY PANEL				Hide ☐
Applicant or License Holder				Hide ☐
Company Name: Co				
Street/Suite/Land Location: M				Include on Label ☐
City: V	Include on Label ☐	Province : Manitoba		Include on Label ☐
Country: Canada		Postal Code: M1M1M1		
Additional License Holder Information				

All fields within the A – Medicinal Ingredient subsection are fixed based on information entered in the ePLA. These fields cannot be revised. See figure 39.

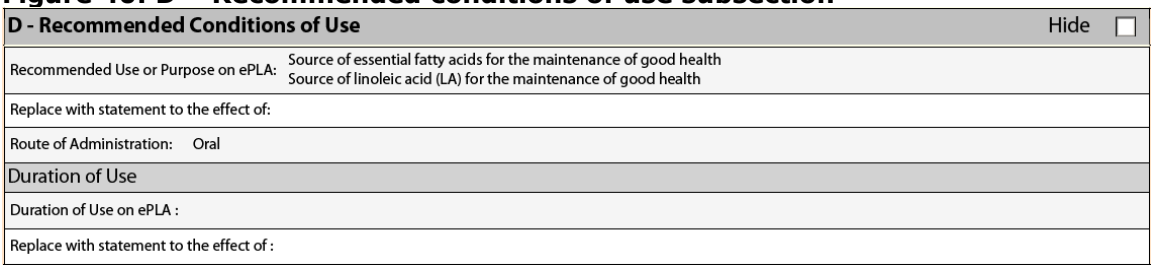
Figure 39: A – Medicinal ingredient subsection



A -Medicinal Ingredient	Hide ☐
Ingredient: 1	Hide ☐
Proper Name : Borago officinalis L. (Boraginaceae)	
Common Name : Borage oil	
Source : Borago officinalis - Seed	
Quantity per Dosage Unit: 1 Grams	
Additional Quantity and Unit:	

The fields within subsection D - Recommended Conditions of Use are populated from information in the ePLA and may be replaced with a statement to the effect; as in Figure 40: D - Recommended Conditions of Use Subsection, Figure 41: Recommended Dose Subsection, and Figure 42: Risk Information Subsection

Figure 40: D – Recommended conditions of use subsection



D - Recommended Conditions of Use	Hide ☐
Recommended Use or Purpose on ePLA:	Source of essential fatty acids for the maintenance of good health Source of linoleic acid (LA) for the maintenance of good health
Replace with statement to the effect of:	
Route of Administration: Oral	
Duration of Use	
Duration of Use on ePLA :	
Replace with statement to the effect of :	

Figure 41: Recommended dose subsection

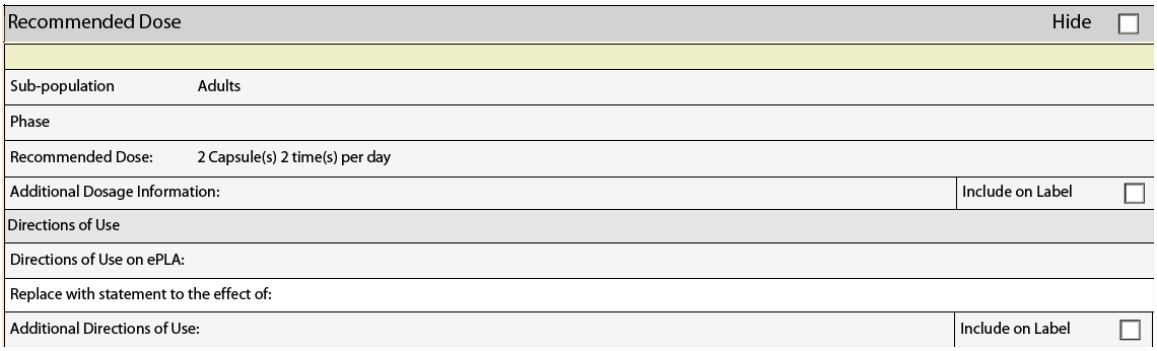
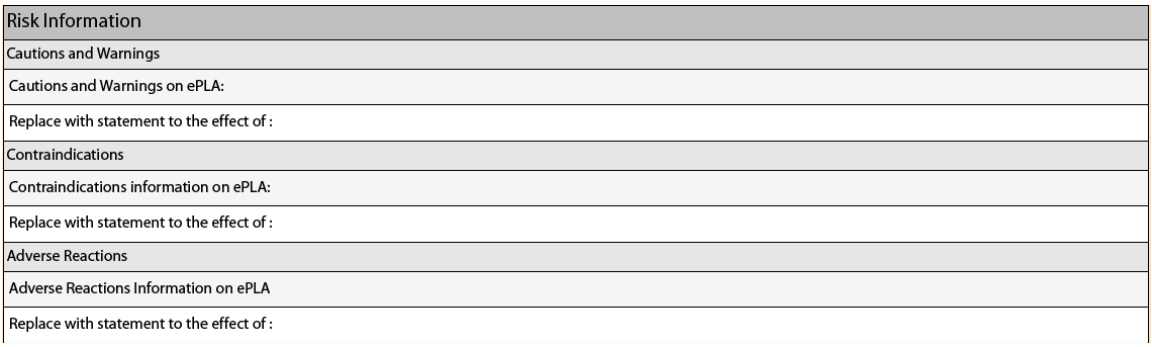
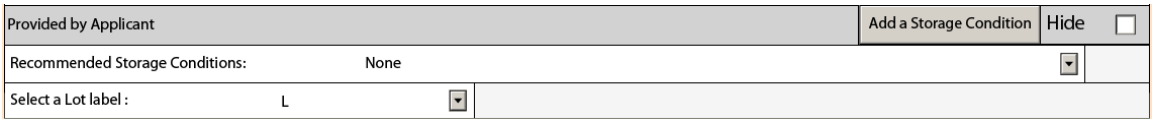


Figure 42: Risk information subsection



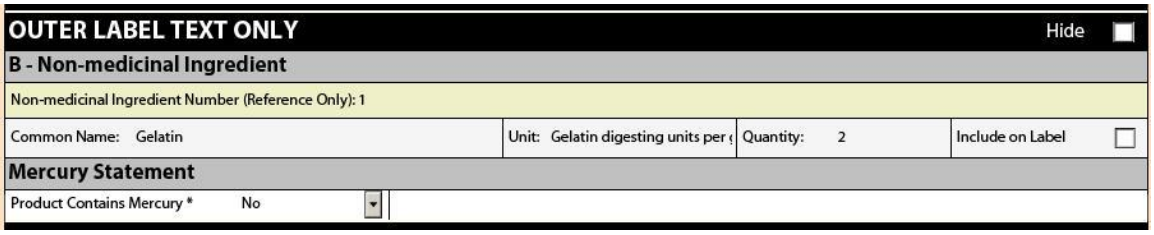
Within the Provided by Applicant subsection, as in Figure 43: Provided by Applicant Subsection below, there exist optional additional fields that may be completed: Recommended Storage Conditions (for which the default value is "None"), and the display of the lot number.

Figure 43: Provided by applicant subsection



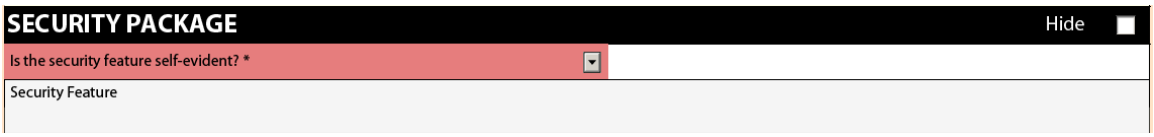
Outer label text only: The Outer Label Text Only section, such as in Figure 44: Outer Label Text Only Section below contains two subsections: B -Non-Medicinal Ingredient and Mercury Statement. The fields within the B -Non-Medicinal Ingredient subsection cannot be changed using the Label Text Editor; they can only be changed by modifying them in Part 4 of the ePLA form. If the product contains mercury, you must specify "Yes" in the **Product Contains Mercury** field of the Mercury Statement subsection. A mandatory field entitled **Quantity of Mercury Statement** will then appear and will need to be filled.

Figure 44: Outer label text only section



Security package: All fields within the Security Package subsection, illustrated in Figure 45: Security Package subsection below, are mandatory fields on the label. If the security feature is not self-evident in the product packaging, then a Security Feature statement must be specified.

Figure 45: Security package subsection



Specialized labelling - inner and/or outer: The content of the Specialized labelling section depends on the application type. For applications of type Compendial, Traditional, Non-traditional and TPD Category IV, the Specialized Labelling -Inner and/or Outer section contains five optional subsections to be completed as applicable:

1. Pressurized Container;
2. Cautionary Statements;
3. Organic Product Statements;
4. Irradiated Product Statements; and
5. Eucalyptus/Camphor Product Statement

For the three homeopathic application types, the Specialized Labelling -Inner and/or Outer section also contains the five optional subsections listed above along with an additional Homeopathic Medicines Labelling subsection.

Other label functions: The label text can be viewed at any time while in the Label Text Editor by selecting the "***View Label Tex***" ***t*** button. The label text can be printed at any time by selecting the " ***Print Label*** " button.

Viewing the label text by selecting the "***View Label Text***" button makes it easier to identify any required changes. Should the changes be required in other parts of the ePLA (for example Part 4), it is best to group the changes together.

When viewing the label text, the label text can be copied to another software application, such as Microsoft Word or Notepad by performing the following:

1. Select the "***Copy Label***" button;
2. Position the cursor within the Copy Label text;
3. Press the Control-A keys to select all text;
4. Press the Control-C keys to copy the text to the Windows clipboard; and
5. Paste the label text from the Windows clipboard into the software application for additional modifications and/or editing.

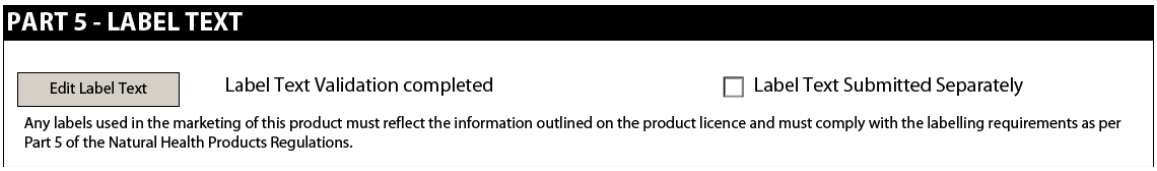
Please note that copying the label text elsewhere in this way is a "one-way" operation. Label text modified within another software application cannot be imported back into the Label Text Editor and subsequently cannot be validated within the ePLA Form. This means that if you wish to use the modified label text for the Product Licence Application, you must therefore submit the modified text separately from the ePLA (see Section 3.6.3 - Label Text Submitted Separately below).

Once all of the desired label text changes have been entered along with the mandatory label text information, the text must be validated by selecting the "***Validate***" button. If some mandatory fields have not been specified, the fields in error will have a coloured background.

Figure 46: Successful label text validation result

When the label text is validated successfully, a message will be displayed as shown above Figure 46: Successful Label Text Validation Result. The Label Text Editor can now be closed by selecting the "***Close***" button. The Label Text Editor can in fact be closed at any time by selecting the "***Close***" button. The result of a successful label text validation is shown below in Figure 47: Successful Label Text Validation in ePLA.

Figure 47: Successful label text validation in ePLA



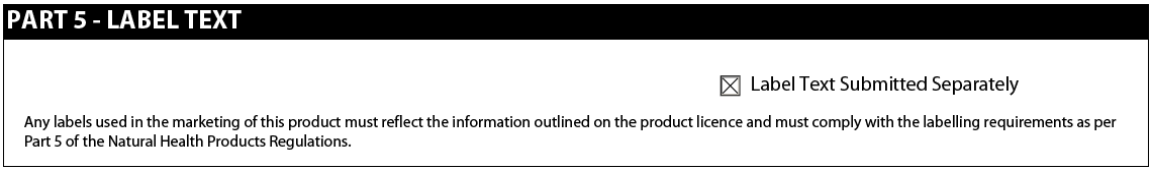
Once all issues with Label Text have been resolved, the Label Text has been validated successfully and the Label Text Editor has been closed, click the "***Continue***" button on the ePLA. This step indicates that Part 5 of the form is complete.

For more information on labelling Natural Health Products, refer to the Labelling Guidance Document.

3.6.3 Label text submitted separately

If you intend to submit the label text separately rather than generate it as part of the ePLA, click the "***Label Text Submitted Separately***" checkbox within Part 5 - Label Text of the ePLA Form, as illustrated in Figure 48: Label Text Submitted Separately Checkbox .

Figure 48: Label text submitted separately checkbox



3.7 Animal tissue form

An Animal Tissue Form (ATF) is added to the ePLA each time "Yes" is selected in response to any of the four Animal Tissue questions:

- For medicinal ingredients, in Part 4 – Section A
- For processing of ingredient question (for homeopathic ingredients only), in Part 4 – Section A
- For non-medicinal ingredients, in Part 4 – Section B
- For ingredients used in processing question, in Part 4 – Section C

The following message in Figure 49: Animal Tissue Form Added Message is shown when the ATF is added:

Figure 49: Animal tissue form added message

For medicinal ingredients and for non-medicinal ingredients, the ATF is pre-filled with the ingredient name and the "Ingredient" value is selected.

For ingredient(s) used in processing, the ingredient name is not populated, but the "in processing of product" value is selected.

Note that the pre-filled values cannot be changed as they represent the information entered in Part 4 of the ePLA. If additional information regarding Animal Tissue must be provided, use the "***Add another Animal Tissue Form***" button to generate more forms as needed so all information is captured. "***The "Return to Part 4***" button allows you to return to the end of Part 4 after having completed the Animal Tissue Forms.

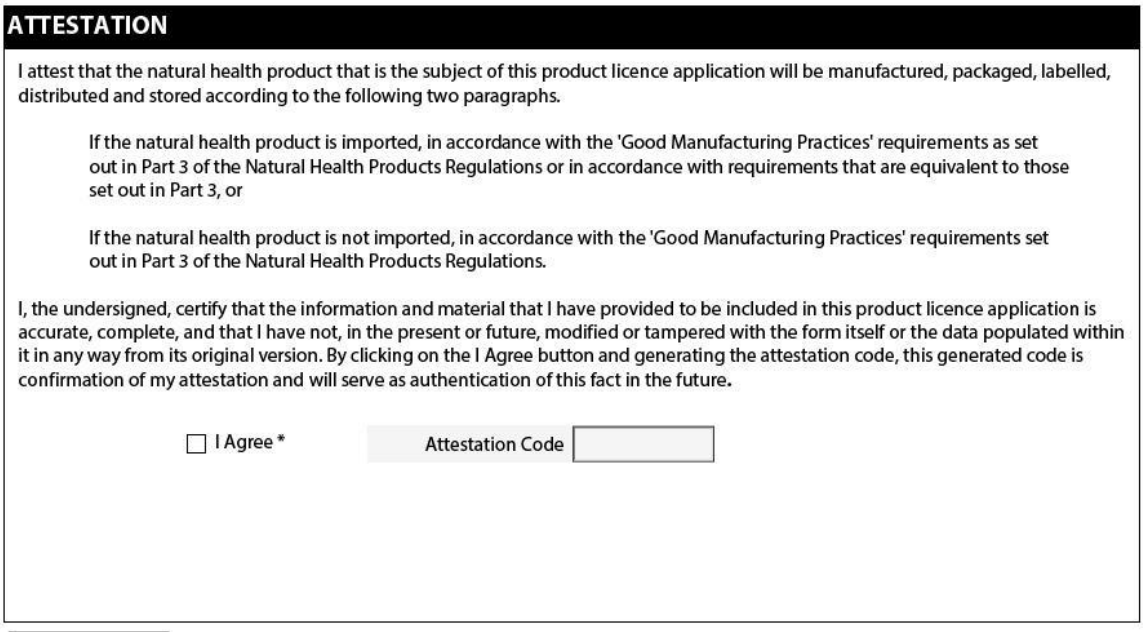
For successful finalization of the ePLA, all required fields of each ATF must be completed – including the "**I Agree**" box at the bottom of each ATF.

3.8 Product licence application (finalize)

Step 1: Attestation

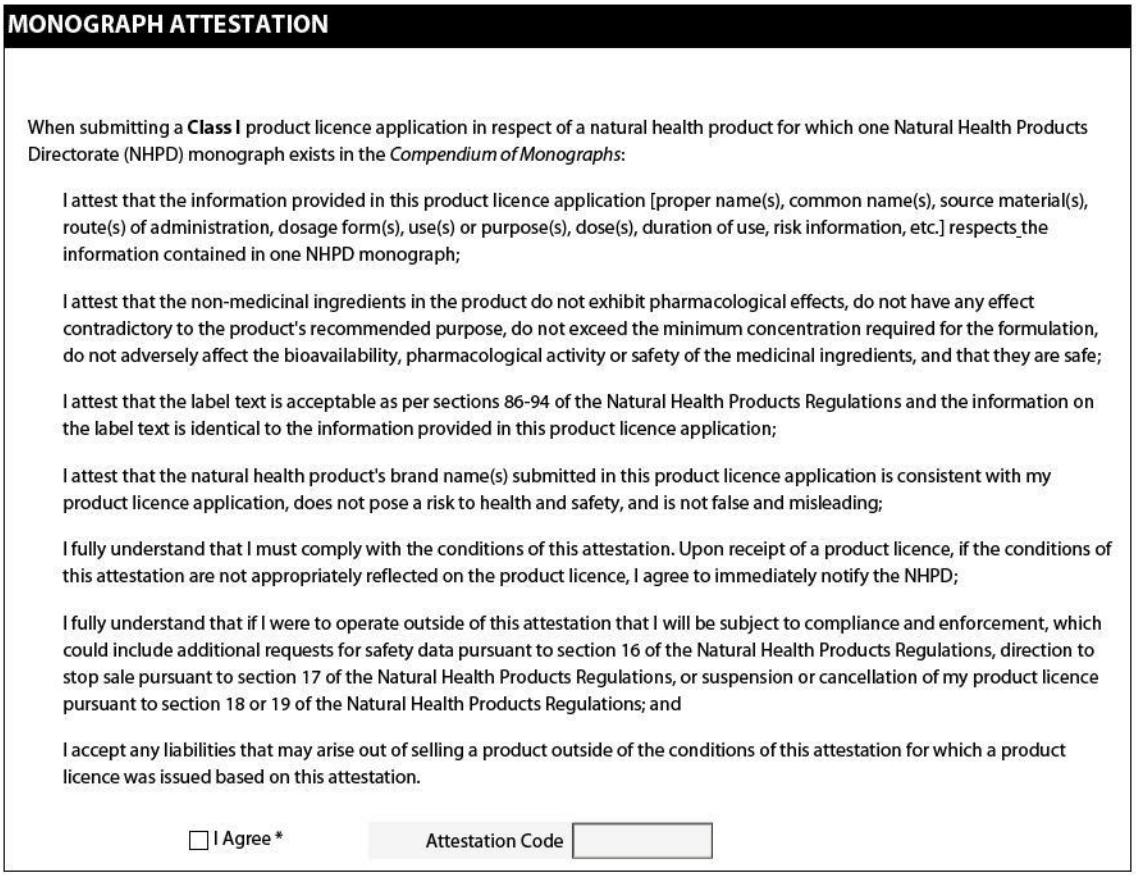
Once all parts of the ePLA have been validated, one or two Attestation boxes will appear. For applications of type 'Compendial' only, there will be two attestations. The attestation shown in Figure 50 below is common to all application types. Selecting the "I Agree" checkbox signifies that the senior official of the company applying for the licence (defined in Part 1, Block 'B') attests to the provided statements. Upon selection, the block displays an Attestation Code.

Figure 50: Attestation block common to all application types



For applications of type Compendial, a second attestation, as shown in Figure 51 below, will be present. Once again, selecting the "I Agree" checkbox signifies that the senior official of the company applying for the licence attests to the provided statements. Upon selection, the block displays an Attestation Code.

Figure 51: Attestation block for Compendial applications



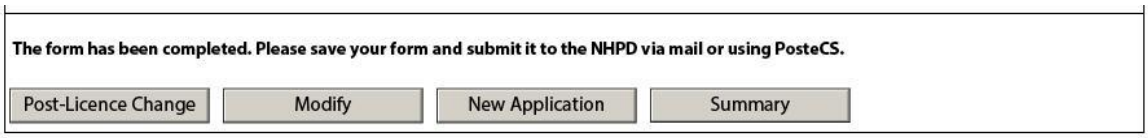
The "***Finalize***" button will appear at the end of the form after all the subforms (i.e. after any ATFs).

Step 2 - Finalize

After the Attestation has been endorsed by selecting the "**I Agree**" checkbox, select the "***Finalize***" button to do a final validation of all parts of the ePLA.

Once all finalization issues are resolved, the form finalization displays at the top and bottom of the form, see Figure 52: Successful Form Finalization Message below.

Figure 52: Successful form finalization message



The finalized form also is assigned a unique tracking number displayed at the top of each page. This tracking number will remain the same regardless of the number of times the finalized form is modified.

TIP: Prior to finalizing your form, the NHPD recommends that you save a copy of your ePLA to avoid potential issues with the ePLA's tracking number in the future. We recommend the following steps:

1. The applicant will enter all information pertaining to their product into the ePLA.
2. The applicant will be asked to finalize their ePLA. At this point **they must save the ePLA prior to finalizing using a unique name**. (e.g. Garlic123456Unfinalized.pdf)
3. The applicant will finalize the ePLA and save it again with a different name (e.g. Garlic123456Finalized.pdf)
4. The applicant will submit the finalized version, but keep both ePLAs on file. Any time the applicant needs to submit a new application to the NHPD, they are free to **modify the unfinalized** version of their ePLA and follow the same steps listed above.

Step 3 – Assemble and submit

After finalization, as indicated in the finalization message, the completed form is ready to be saved on your workstation and then submitted as per the Product Licence guidance document. Should you choose to print the electronic form and send it to NHPD via regular mail, please note that the electronic form will only print properly once certain conditions are met. In order to print properly, the electronic form must be finalized, saved, and closed first. When the form is ready to be printed, the closed finalized form can be reopened and then printed.

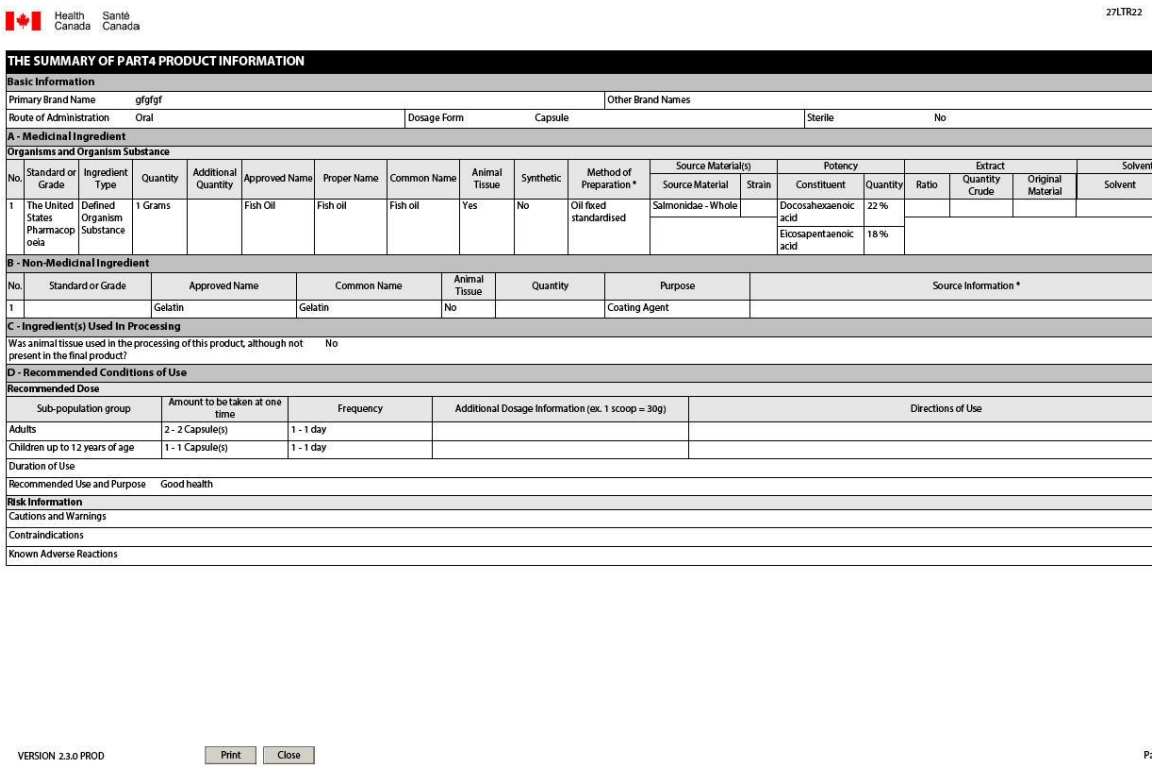
3.8.1 Product information summary

The Summary of Product Information displays the contents of Part 4 by showing each ingredient, whether medicinal or non-medicinal, in a single line.

The summary can be viewed after completing an application by clicking the "***Summary***" button of the bottom finalization message.

This will generate an onscreen report of one or more pages that can be printed as desired, as shown in Figure 53: Product Information Summary report below.

Figure 53: Product information summary report



Health Canada Santé Canada

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THE SUMMARY OF PART4 PRODUCT INFORMATION

Basic Information

Primary Brand Name	gfgfgf	Other Brand Names	
Route of Administration	Oral	Dosage Form	Capsule
Sterile	No		

A - Medicinal Ingredient

Organisms and Organism Substance

No.	Standard or Grade	Ingredient Type	Quantity	Additional Quantity	Approved Name	Proper Name	Common Name	Animal Tissue	Synthetic	Method of Preparation *	Source Material(s)		Potency		Extract			Solvent
											Source Material	Strain	Constituent	Quantity	Ratio	Quantity Crude	Original Material	Solvent
1	The United States Pharmacopoeia	Defined Organism Substance	1 Grams		Fish Oil	Fish oil	Fish oil	Yes	No	Oil fixed standardised	Salmonidae - Whole		Docosahexaenoic acid	22 %				
													Eicosapentaenoic acid	18 %				

B - Non-Medicinal Ingredient

No.	Standard or Grade	Approved Name	Common Name	Animal Tissue	Quantity	Purpose	Source Information *
1		Gelatin	Gelatin	No		Coating Agent	

C - Ingredient(s) Used In Processing

Was animal tissue used in the processing of this product, although not present in the final product? No

D - Recommended Conditions of Use

Recommended Dose

Sub-population group	Amount to be taken at one time	Frequency	Additional Dosage Information (ex. 1 scoop = 30g)	Directions of Use
Adults	2 - 2 Capsule(s)	1 - 1 day		
Children up to 12 years of age	1 - 1 Capsule(s)	1 - 1 day		

Duration of Use

Recommended Use and Purpose Good health

Risk Information

Cautions and Warnings

Contraindications

Known Adverse Reactions

VERSION 2.3.0 PROD Print Close P

To return to the ePLA, select the "***Close***" button.

4.0 Using the ePLA form after submission

4.1 Corrections to a submitted form

The "***Modify***" button can be used to update an already-submitted application in response to a notice from the NHPD or if modifications are required during the application process. The NHPD uses the tracking number on the form to locate and replace the previous version.

The "***Modify***" button must only be used when responding to an information request from NHPD or doing any modifications to the same product during the application process. It should not be used to change the content of refused ePLAs or to create new applications from previously finalized applications with similar content. The latter actions will result in duplicate tracking numbers at NHPD which cause serious delays in file processing.

After selecting the "***Modify***" button in order to respond to an information request as part of the application process and making the desired change(s), Parts 1 through 4 need to be re-validated by selecting the "***Continue***" button at the end of Part 4. In Part 5, the label text also needs to be re-validated, and the application form needs to be successfully finalized before the updated form can be submitted.

4.2 Post-licence activity

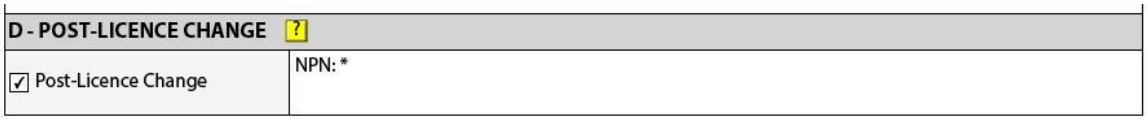
Following issuance of a product licence, if any changes are made, as stated in Sections 11 and 12 of the *Natural Health Products Regulations*, the ePLA can be used to submit the post-licence amendment or notification.

These notifications and amendments follow the same basic approach as the original application - the original ePLA is modified to reflect the desired changes. This ensures the integrity of the Product Licence Application.

For licensed products which were submitted before the availability of the ePLA 1.4.1, which was released in November 2010, the applicant must capture the original product information along with the desired changes using the current ePLA. Complete and finalize a new form for the original product by following the instructions in this User Guide.

Select the "***Post-Licence Change***" button from the form finalization message (see Figure 51: Successful Form Finalization Message). This makes a copy of Parts 1 to 4 of the original ePLA and clears the tracking number. A new section appears in Part 2 as shown in Figure 54 - D. Post-Licence Change. This section indicates that this ePLA is for a previously-licensed product and has a location to capture the NPN for that product. The eight digit NPN must be provided. You can then complete the form with the post-licence changes (including Part 5 – Label Text), successfully finalize it (to get a new Tracking Number) and send it in.

Figure 54: D. Post-licence change



4.3 New application activity

A new Product Licence Application form can be generated from a finalized ePLA by selecting the "***New Application***" button from the form finalization message. This makes a copy of Part 1 only and clears the tracking number. It also provides the option to select the language of the form.

4.4 Importing an application

In order to use the latest version of the ePLA with information already entered in an older version of the electronic form, one can use the Import/Export feature of Adobe forms. Currently, this will only work to move information found in an ePLA of version 2.0.1 or greater into an ePLA of version 2.1 or greater. The import feature does not work for ePLAs of version 1.4.4 or older into version 2.1.

To export information from an ePLA of version 2.0.1 (or greater) into a version 2.1 (or greater) of the electronic form, here are the steps to follow:

(i) Open the ePLA of version 2.0.1 (or greater).

(ii) From the '**Forms**' menu at the top, select **'Manage Form Data**', and then **'Export Data**'.
(iii) Save the xml export file at a convenient location.
(iv) Open a new ePLA of version 2.1 (or greater).
(v) From the '**Forms**' menu at the top, select **'Manage Form Data**' and then **'Import Data**'.
(vi) Select the previously exported xml file.
(vii) The information transfer will take a few seconds. The content of the new ePLA should be checked to confirm that all data was properly moved. A transferred finalised form may have to be refinalised.