Product Licence Application Form

Natural Health Products Directorate

[PLA-FORM]

Foreword

The Product Licence Application form (along with the label text and supporting safety, efficacy and quality information, when required) may be used to apply for a natural product number (NPN or DIN-HM in the case of homeopathic medicines) from the Natural Health Products Directorate (NHPD). It may also be used to apply for an amendment or notification of changes for products that are already licenced (NPN or DIN-HM for homeopathic products).

There are different types of applications that may be made for a product licence, each with its own submission requirements. The requirements for each of these types of applications are listed below. For more detailed information, refer to the Product Licensing guidance document and the Management of Product Licence Applications for Natural Health Products guidance document.

Table 1 – Requirements based on application type

Requirements	**Application Type**						
	Compendial (NHPD Monograph)	Traditional Claim	Non-traditional Claim	Homeopathic		TPD Category IV/ Labelling Standard	NHPD & Homeopathic Labelling Standards[1]
				Specific Recommended use	Non-specific Recommended Use		
Product Licence Application form	X	X	X	X	X	X	X
NHPD Label text	X	X	X	X	X	X	X
References	X*	X	X	X	X	X	X*
Finished Product Specifications	Not applicable	X	X	X	X	X	X
Animal Tissue form (if applicable)	X	X	X	X	X	X	X
Safety, Evidence and/or Quality Summary Report	Not applicable	X**	X**	Not applicable	Not applicable	Not applicable	Not applicable
Cover Letter	Optional	Optional	Optional	Optional	Optional	Optional	Optional

*It is not required to include a copy of the Monograph or Labelling Standard.

**A summary report is optional and may be included to help explain information present to support the product licence application.

[1]If selecting one of these two application types, please indicate either Non-Traditional or Homeopathic on the Product Licence Application form.

When completing the PLA-FORM, this covering Foreword and Guideline should be deleted.

Health Canada Santé Canada

* - denotes mandatory
** - if yes, complete Animal Tissue Form

PRODUCT LICENCE APPLICATION FORM
Natural Health Products Directorate

Protected when completed

HEALTH CANADA USE ONLY		3. Date/Time of Receipt
1. Submission Number	2. File Number	

Please refer to the Guide for instructions on how to complete this application.

PART 1 – APPLICANT AND CONTACT INFORMATION

A. – APPLICANT OR LICENSEE (This is the product licence holder)

4. Applicant/Company Name*			5. Company Code (If known)
6. Address: Street/Suite/PO Box*			
7. City – Town*	9. Province – State*	8. Country*	10. Postal/ZIP Code*

B. – SENIOR OFFICIAL (This is the name of the principal contact person for the applicant/company)

11. Name ☐ Mr. ☐ Ms. ☐ Dr. Surname*_____ Given Name*_____		12. Title	13. Language preferred: ☐ English ☐ French
14. Company Name (* if different from Applicant/Licensee)			**15. Address same as "A"** ☐
16. Street/Suite/PO Box*			
17. City – Town*	19. Province – State*	18. Country*	20. Postal/Zip Code*

21. Telephone No.*	Ext.	22. Fax No.	23. E-mail

C. – CONTACT FOR THIS APPLICATION (This is the contact person for product-specific questions)

24. Contact same as "B" ☐		26. Title	27. Language preferred: ☐ English ☐ French
25. Name ☐ Mr. ☐ Ms. ☐ Dr. Surname*_____ Given Name*_____			
28. Company Name (*if different from Applicant/Licensee)			**29. Address same as "A"** ☐
30. Street/Suite/PO Box*			
31. City – Town*	33. Province – State*	32. Country*	34. Postal/Zip Code*

35. Telephone No.*	Ext.	36. Fax No.	37. E-mail

Attach separate sheets (same format) if necessary. Number of pages attached: _____

D. – REPRESENTATIVE IN CANADA (Only required where Address in "A" is not in Canada)

38. Contact same as "C" ☐		40. Title	41. Language preferred: ☐ English ☐ French
39. Name ☐ Mr. ☐ Ms. ☐ Dr. Surname*_____ Given Name*_____			
42. Company Name (* if different from Applicant/Licensee)			**43. Address same as "C"** ☐
44. Street/Suite/PO Box*			
45. City – Town*	47. Province – State*	46. Country* **Canada**	48. Postal/Zip Code*

49. Telephone No.*	Ext.	50. Fax No.	51. E-mail

E. – CONTACT TO WHOM THE PRODUCT LICENCE IS TO BE SENT:

52. As Above: B:☐ C:☐ D: ☐
Not Applicable:☐ Name:_____
(check only one box)

PART 2 – SUBMISSION TYPE

A. – PRODUCT LICENCE APPLICATION

53. Indicate the type of application (*select one only)

☐ Compendial ☐ Traditional claim ☐ Non-traditional claim ☐ Homeopathic ☐ TPD Category IV/Labelling Standard

☐ Homeopathic DIN (DIN#___________________) ☐ Transitional DIN (DIN#___________________)

54. Is this formulation hypothetical? ☐ Yes ☐ No

55. NPN/DIN-HM #_______________________________ (* - required for Section **B**. **C, and D**. only).

B. – MONOGRAPH REVISIONS AFFECTING AN EXISTING PRODUCT LICENCE

56. ☐ Yes, revisions to the published NHPD Compendial Monograph affect the NPN above.
NHPD Compendial Monograph:____ Date: ____

C. – PRODUCT LICENCE – AMENDMENT

57. Indicate the affected change to the NPN/DIN-HM above. (select one or more)

☐ Potency

☐ Source material of any of its medicinal ingredients

☐ Addition or substitution of a non-medicinal ingredient not on the NHPD List of Acceptable non-medicinal ingredients

☐ Specification

☐ Deletion or modification of risk information on any labels

☐ Recommended dose

☐ Change to Animal Tissue Form(s)

☐ Recommended use/purpose

☐ Change to or from synthetically manufactured

☐ Recommended duration of use

☐ Change to manufacturing information

D. – PRODUCT LICENCE – NOTIFICATION

58. Indicate the type of change(s) that have been made to the NPN/DIN-HM above. (select one or more)

☐ Addition or substitution of any of its proposed non-medicinal ingredient other than those originally authorized for the product.

☐ Change to the common name of any of its medicinal ingredients

☐ Addition of risk info on any of its labels

☐ Change to the name, address, telephone number, fax number, and/or electronic mail address of the manufacturer, packager, labeller, importer, and distributor.

☐ Sale under a brand name other than the one(s) originally authorized for the product license

☐ Change to the proper name of any of its medicinal ingredients

☐ Change to the name, address, telephone number, fax number, and/or electronic mail address of the applicant or Canadian representative.

☐ Change to a Site Licence number for a Canadian manufacturer, packager, labeller, or importer.

☐ Addition of a site associated with the product.

E. – SUBMISSION CONTENT

59. Type of supporting documents, by volume: check type that is applicable and indicate the volume in which the document is submitted. Volume #

Number of Volumes: _______________	☐ Animal tissue form(s)	#: ____________	_________
☐ Product licence application form	☐ Designated Party Authorization form:		_________
☐ Additional pages for Product Information	☐ Label Text	#: ____________	_________
☐ Additional pages for Site Information	☐ TPD Label Text (Transitional DIN or Homeopathic DIN)	#: ____________	_________
☐ Evidence Summary Report:	☐ Quality Summary Report:		_________
☐ Safety Summary Report:	☐ Other, Claim Evidence:		_________

F. – REFERENCE SUBMISSION (if applicable)

60. Other submission that contains the evidence to support the safety, efficacy and/or quality of this particular submission.

Company #: ________________ File #: ___________________ Submission #: ______________ NPN/DIN-HM #: _______________

Contains information to support: ☐ Safety ☐ Efficacy ☐ Quality Letter of access(es) enclosed: ☐ Yes ☐ Not Applicable

Company #: ________________ File #: ___________________ Submission #: ______________ NPN/DIN-HM #: _______________

Contains information to support: ☐ Safety ☐ Efficacy ☐ Quality Letter of access(es) enclosed: ☐ Yes ☐ Not Applicable

Company #: ________________ File #: ___________________ Submission #: ______________ NPN/DIN-HM #: _______________

Contains information to support: ☐ Safety ☐ Efficacy ☐ Quality Letter of access(es) enclosed: ☐ Yes ☐ Not Applicable

G. – NHPD MASTER FILE (if applicable)

61. Master file that contains the evidence to support the safety, efficacy and/or quality of this particular submission.

Master File #: ____ Letter of access enclosed: □ Yes □ Not Applicable

Contains information to support: ☐ Safety only ☐ Efficacy only ☐ Quality only ☐ Complete submission

Attach separate sheets (same format) if necessary. Number of pages attached: _________

PART 3 – SITE INFORMATION

62. Company Name			63. ☐ Manufacturer SL# __________ ☐ Packager SL# __________ ☐ Labeller SL# __________ ☐ Importer SL# __________ ☐ Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country	68. Postal Code – Zip Code	
62. Company Name			63. ☐ Manufacturer SL# __________ ☐ Packager SL# __________ ☐ Labeller SL# __________ ☐ Importer SL# __________ ☐ Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country	68. Postal Code – Zip Code	
62. Company Name			63. ☐ Manufacturer SL# __________ ☐ Packager SL# __________ ☐ Labeller SL# __________ ☐ Importer SL# __________ ☐ Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country	68. Postal Code – Zip Code	
62. Company Name			63. ☐ Manufacturer SL# __________ ☐ Packager SL# __________ ☐ Labeller SL# __________ ☐ Importer SL# __________ ☐ Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country	68. Postal Code – Zip Code	
62. Company Name			63. ☐ Manufacturer SL# __________ ☐ Packager SL# __________ ☐ Labeller SL# __________ ☐ Importer SL# __________ ☐ Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country	68. Postal Code – Zip Code	
69. Attach separate sheets (same format) if necessary. Number of pages attached: _________			

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PART 4 – PRODUCT INFORMATION

70. Primary Brand Name*

71. If necessary, attach a separate sheet with other brand names. Number of pages attached: _____

A. – MEDICINAL INGREDIENT(S)

72. Ingredient No.	73. Standard or Grade	74. NHPD Compendial Monograph		75. Proper Name*	76. Common Name	77. Quantity per Dosage Unit*	78. Synthetic*		79. Animal Tissue**	
		Name	Date				Yes	No	Yes	No
1.										
2.										
3.										
4.										
5.										
6.										
7.										
8.										
9.										
10.										
11.										
12.										

80. Ingredient No.	81. Potency (if applicable)		84. Source Information* (if more than one enter on new line)	85. Extract (if applicable)				90. Method of preparation
				86. Ratio	87. Quantity Crude Equivalent	Original Material		
	82. Amount	83. Constituent				88. Fresh	89. Dry	
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								

91. Attach separate sheets (same format) if necessary. Number of pages attached: _____

Health Canada Santé Canada

PART 4 – PRODUCT INFORMATION

B. – NON-MEDICINAL INGREDIENT(S)

92. Ingredient No.	93. Proper Name	94. Common Name*	95. Purpose*	96. Animal Tissue Used**	
				Yes	No
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8,					
9.					
10.					
11.					
12.					

97. Ingredient No.	98. Standard or Grade	99. Quantity	100. Source Information (if more than one enter on new line)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8,			
9.			
10.			
11.			
12.			

C. – INGREDIENT(S) USED IN PROCESSING

101. “Was animal tissue used in the **processing** of this product, although not present in the final product?” ** ☐ Yes ☐ No

PART 4 – PRODUCT INFORMATION

D. – RECOMMENDED CONDITIONS OF USE

102. Recommended Use or Purpose*

103. Dosage Form (one only)*	104. Sterile* ☐ Yes ☐ No	105. Route of Administration*

106. Duration of Use (if any)

Recommended Dose (repeat for each sub-population group)

107. Sub-population group*	108. Amount to be taken at one time:		111. Frequency	112. Directions of Use
	109. No. of Dosage Units* (e.g. 1, 2, etc.)	110. Dosage Unit* (e.g. capsule, tsp, etc.)		

Risk Information

113. Cautions and Warnings*

114. Contraindications*

115. Known Adverse Reactions*

ATTESTATION

"I attest that the natural health product that is the subject of this product license application will be manufactured, packaged, labelled, distributed and stored:

a) If the natural health product is imported, in accordance with the 'Good Manufacturing Practices' requirements as set out in Part 3 of the Natural Health Products Regulations or in accordance with requirements that are equivalent to those set out in Part 3, or

b) If the natural health product is not imported, in accordance with the 'Good Manufacturing Practices' requirements set out in Part 3 of the Natural Health Products Regulations.

I, the undersigned, certify that the information and material included in this product licence application is accurate and complete".**

116. Name of Authorized Senior Official[1] (print)*	117. Signature*	118. Date*
		y y y y m m d d
If the signing official is a third party acting on behalf of the Senior Official of the applicant company designated in Part 1 of the application, a designated Party Authorization form must be signed by the Senior Official and filed with the complete application.		

Guide for Completing the Product Licence Application Form

Section #	GUIDE
1-3	Health Canada Use Only
	PART 1 – APPLICANT AND CONTACT INFORMATION
Block A	**APPLICANT OR LICENSEE**
	Information pertaining to the company in whose name the NHP application is filed and the product licence will be registered (the applicant will be referred to as the licensee once a licence has been granted). Please note, for product licence submissions, the licensee/applicant is not necessarily the company that fabricates the product (e.g. may be the distributor of the product or the importer, etc.). The licensee/applicant is responsible for: • submitting the complete product licence application package to the NHPD for assessment; • designating a representative in Canada if the senior official is outside Canada; • ensuring the NHP is properly labeled; • providing information or samples to the NHPD, if requested; • submitting any notifications and amendments; • stop sale, if requested by the NHPD; • providing site information before commencing sale of a NHP; • maintaining records, as required; reaction reporting; and recall reporting.
4	**Applicant/Company Name:** Indicate the full legal name of the applicant/company in whose name the subject NHP application is being filed. Do not abbreviate the applicant/company name.
5	**Company Code:** The number assigned to each applicant company by the NHPD. This number will be indicated in the acknowledgement letter sent by the NHPD to acknowledge the receipt of a submission. This information need only be provided if the company code is known. **If not known, leave blank.**
6-10	Provide the full mailing address of the applicant/company identified in Section 4. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (6), the city/town (7), the province/state (9), the country (8) and the postal or zip code (10). Include the PO Box number (6) if a post office box is used.
Block B	**SENIOR OFFICIAL**
	A senior official must always be designated for the applicant company. The principal contact person for the licensee/applicant, at the address given, is to whom regulatory mail is sent. This is not the contact person for product application-specific questions, but the person who will represent the company. This should be a senior person in the company such as a Chief Executive Officer (CEO) or director. In some cases, especially small businesses, one person may be indicated as both the senior official and contact for this application. For each NHPD-issued company code, there must only be one associated senior official. If the senior official of the applicant company changes, the NHPD must be notified of this change.

Section #	GUIDE
11-23	Provide the name of the Senior Official (11) and the information needed to contact that individual, i.e. company name (if different than applicant/licensee) (14), full mailing address (16-20), telephone and fax numbers (21-22), position/title (12), e-mail address (23), and language preference (13). The full mailing address (16-20) is not required, if the Senior Official has the same address as the applicant or licensee identified in sections 6 to 10 (15). If no language of preference is indicated (13), by default the language of communication will be that of the cover letter or majority of the product licence application.
Block C	**CONTACT FOR THIS APPLICATION**
	The contact for this application is the person to whom NHPD will direct product specific questions. This may be an employee of the licensee/applicant, or an individual contracted from another company on behalf of the licensee/applicant. **There may be more than one contact indicated per application. However, all non-regulatory mail will be sent to the person indicated in Part 1, Box C on the Product Licence Application form.** All other contacts for this application may: send responses to NHPD, call with inquiries and answer product specific questions. These additional contacts may be listed on a separate sheet using the same format as that outlined in Block C (please indicate how many additional separate sheets are attached for this purpose at the bottom of Block C).
24-37	Provide the name of the contact for this application (25) and the information needed to contact that individual, i.e., company name (if different than applicant/licensee) (28), full mailing address (30-34), telephone and fax numbers (35-36), position/title (26), e-mail address (37), and language preference (27). The full mailing address (30-34) is not required, if the contact for this application has the same address as the applicant or licensee identified in sections 6 to 10 (29). If the Senior Official is also the contact for this application, please check the box in section 24.If no language of preference (27) is indicated, by default the language of communication will be that of the cover letter or majority of the product licence application.
Block D	**REPRESENTATIVE IN CANADA**
	The representative in Canada is the person to whom NHPD will direct regulatory mail and who is responsible for the sale of this product in Canada**. A Representative in Canada is only required to be indicated on the Product Licence Application form if the licensee/applicant's address is outside of Canada.** There must only be one Representative in Canada indicated per application. Any person with a Canadian address may act as the Representative in Canada; however, this person will bear all responsibilities of the licensee/applicant.
38-51	Provide the name of the representative in Canada (39) and the information needed to contact that individual, i.e., company name (if different from applicant/licensee) (42), full mailing address (44-48), telephone and fax numbers (49-50), position/title (40), e-mail address (51), and language preference (41). The full mailing address (44-48) is not required, if the contact for this application has the same address as the contact for this application identified in sections 30 to 34 (43). If the Representative in Canada is also the contact for this application, please check the box in section 38. If no language of preference (41) is indicated, by default the language of communication will be that of the cover letter or majority of the product licence application.

Section #	GUIDE
Block E	**CONTACT TO WHOM THE PRODUCT LICENCE IS TO BE SENT**
52	Once a product licence is granted by the NHPD, the licence and an issuance letter will be sent to the Licensee, with a copy being sent to the contact for the application. In cases where the Licensee is not in Canada, the product licence will be sent to the Canadian Representative, with a copy sent to the Licensee and the contact. Please see the Submission Management guidance document for further information on the licence issuance process.
	Part 2 – Submission type
Block A	**PRODUCT LICENCE APPLICATION**
53	There are different types of applications: compendial, traditional, non-traditional, homeopathic or TPD category IV/labelling standard. Please see Chapter 2 of the *Product Licensing* guidance document for a definition of each type of submission and their related submission requirements. Please indicate only one type of submission.
54	Hypothetical formulations are those which have been described in the Product Licence Application form but are only at the planning stage and have not reached the manufacturing stage. For that reason, certain types of evidence that would be available for a product already manufactured, such as batch records, may not be available. Alternative sources of evidence for the quality information needed to meet the regulatory requirements are described in the *Evidence for the Quality of Finished Natural Health Products* guidance document.
55	The product licence number (NPN/DIN-HM) must be provided when an application respecting a change (i.e. a monograph revision, an amendment or a notification) to a NHP is being made to an existing product licence. Only one product licence number (NPN/DIN-HM) may be indicated per product licence application form. This information is only required if Part 2 - blocks B, C or D are being completed and should not be completed for a new product.
Block B	**MONOGRAPH REVISIONS AFFECTING AN EXISTING PRODUCT LICENCE**
56	If the application is the result of a change to a published NHPD Compendial Monograph, please place a check mark in the box and provide the name of the NHPD Compendial Monograph. Please ensure that a NPN has been provided in Section 55. Revisions to the published NHPD monographs will occur from time to time. When the revision affects the proper name or safety and efficacy of products licensed for sale using an NHPD monograph, NHPD will issue a letter to all affected product licence holders of the revision. Please see the Compendium of Monographs for further information on the types of changes that may occur and the requirements for each type of change.

Section #	GUIDE
Block C	**PRODUCT LICENCE - AMENDMENT**
57	Please fill in this section only if a product already has a NPN or DIN-HM and an amendment to the product is being requested. A product licence, once granted, may be changed. Amendments may only be submitted for products that have already been granted a licence (i.e. unsolicited changes to the product licence application before a licence has been granted are not considered to be amendments). Licensees must amend their product licence when they intend to change information submitted in the previously approved product licence application which may affect the safety, efficacy, and quality of the product. **Amendment applications must be approved by NHPD before the amended product is sold.** The licence information will be revised accordingly and will include the amended and original date of issue. If a product licence is amended, a product not affected by the amendment may not be sold (i.e. the product that was covered by the licence before the amendment had been approved, can no longer be sold, the product sold must reflect the amended licence only). An example of a change that would require an amendment is a change in the recommended dose. When requesting an amendment, please ensure that the licence number of the product to be amended is provided (Section 55).
Block D	**PRODUCT LICENCE – NOTIFICATION**
58	Please fill in this section only if a product already has a NPN or DIN-HM and a notification type change is being made. A notification refers to a change in the product licence that does not affect the safety, efficacy, and/or quality of the product. Notifications must be made to NHPD within 60 days after the day on which the change was made; notification before the change is not required. An example of this type of change is a change in the contact information for the product licence holder. NHPD requires information of this type to keep its records up to date. When requesting a notification, please ensure that the licence number of the product to be changed is provided (Section 55).
Block E	**SUBMISSION CONTENT**
59	Indicate the supporting documents included with this submission. This section will ensure that the NHPD has received all of the intended documents, including label text, Evidence Summary Report, Safety Summary Report, etc.
Block F	**REFERENCE SUBMISSION**
60	Where related NHP submissions are referenced in the subject submission, provide the company code (see Section 5 above), the file number, the submission number, and the NPN/DIN-HM number (if available). Indicate the summary report being referenced by checking the appropriate box for safety, efficacy, quality, or complete submission. When an applicant wishes to reference another submission, he/she must reference one or more of the summary reports (Safety, Efficacy and/or Quality) in their entirety (i.e. if referencing the safety summary report, the applicant must reference the entire report and not submit any additional safety information). Additional information on referencing other submissions may be found in Chapter 4.1 of the Product Licensing guidance document.

Section #	GUIDE
Block G	**NHPD MASTER FILE**
61	In some circumstances a NHP Master File may be referenced. A NHP Master File may be submitted, when a company would like to submit confidential information on behalf of another company (i.e. supplier submitting confidential manufacturing information on behalf of a manufacturer). Where related NHP submission information is contained in a Master File, please indicate the master file number and the information being supported (i.e. safety, efficacy, quality, or complete submission). When the Master File has not been submitted by the company applying for the licence, a Letter of Access must be included authorizing the NHPD to access the indicated parts of the Master File. Refer to the Master File guidance document for further information on the requirements for a Master file and information that must be included in the Letter of Access. It is the responsibility of the applicant to ensure that a Master File has been submitted on his/her behalf if a Master File is to be referenced.

Section #	GUIDE
	PART 3 – SITE INFORMATION
	Refer to chapter 4.2 of the *Product Licensing* guidance document for additional information.
62	**Company Name:** The name of the company who owns the site. Do not abbreviate the company name.
63	**Site Licence Number:** A number assigned by the NHPD for authorization to manufacture, package, label or import a NHP. Please note that distributors do not require a site licence and only companies with an address in Canada require a site licence from the NHPD. A location may be licensed to manufacture, package, label, import and/or distribute products. For each company name, check all activities which are conducted by that company.
64-68	Provide the full mailing address of the company (i.e. not the site at which the activity is taking place). If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (64), the city/town (65), the province/state (67), the country (66) and the postal or zip code (68). Include the PO Box number (64) if a post office box is used.
69	If there is not sufficient room on the form to complete the information for all companies involved in the production of the product, please attach separate sheets, using the same format (62-68) and providing the same information as requested in the application. State the number of additional pages.

Section#	GUIDE
70	This is the primary brand name under which the product is to be sold. If the product will be sold under more than one brand name, one should be chosen as the primary. This will be the name included in correspondence with NHPD.
71	Other brand names under which the product will be marketed must also be provided. When there are multiple brand names, one name must be indicated as the primary brand name in section 70. If there are additional brand names, please attach separate sheet(s) listing the additional brand names. Please state the number of additional pages.
Block A	**MEDICINAL INGREDIENT(S)**
	Medicinal ingredient is any substance described in Schedule 1 of the Natural Health Products Regulations, a homeopathic medicine or a traditional medicine that is intended to provide pharmacological activity or other direct effect in : a) the diagnosis, treatment, mitigation, or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; or b) restoring or correcting organic functions in humans; or c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health. In other words, the ingredient is considered to be medicinal in nature if it contributes to the therapeutic activity associated with the recommended use or purpose. For products with more than one medicinal ingredient (combination product), refer to chapter 9.0 of the Evidence for Safety and Efficacy of Finished Natural Health Products guidance document. All medicinal ingredients found in the product must be listed as such within the Natural Health Products Ingredients Database (NHPID). Please note that some ingredients within the NHPID have associated limits or restrictions and these must also be considered when filing. In addition, the NHPID also lists some ingredients which are not natural health product ingredients and those are clearly indicated as not acceptable. An entry in the database does not imply that the ingredient has been reviewed for safety. If these ingredients are not listed in the NHPID, applicants are responsible for submitting a request to NHPD to add these ingredients to the database before the application is filed. The application can only be filed once the ingredients are deemed acceptable and added to the database. For more information on how to request the addition of ingredients or other information to the NHPID, please refer to the NHPD Online Solution.
72	The ingredient number corresponds to the ingredient number listed in Section 80 for easy referencing when preparing and reviewing the medicinal ingredients.

Section#	GUIDE
73	If the ingredient conforms to a particular standard or grade (i.e. USP, HPUS), please state that standard here. If no mention is being made on the product label with reference to a particular standard or grade, this field may be left blank. For homeopathic medicines, the standard or grade must be completed. Enter into this box the acronym for the homeopathic pharmacopoeia referenced for each medicinal ingredient. Refer to the Evidence for Homeopathic Medicines guidance document to determine the appropriate acronyms.
74	If the medicinal ingredient conforms to a monograph published by the NHPD, indicate the monograph name and date of publication. For compendial submissions, the monograph must be referenced in its entirety. For non-compendial submissions, the applicant may reference the safety and/or efficacy of a medicinal ingredient covered by an NHPD monograph. If an NHPD monograph is not being referenced for a medicinal ingredient, this column should be left blank.
75	List the proper name of the medicinal ingredient.
76	List the common name of the medicinal ingredient which will appear on the label. NHPD recognizes that the common name and proper name may be the same in some instances, for example calcium. If this is the case, leave the common name field blank. Refer to Chapter 4.3 of the Product Licensing guidance document for additional guidance.
77	List the quantity of the specified medicinal ingredient per dosage unit (for example, per tablet). For tinctures or fluid extracts, the quantity is equal to the volume of the dosage unit. Each medicinal ingredient in the product must have a quantity associated with it. The quantity of medicinal ingredient should be based on the proper name of the medicinal ingredient. For example, the quantity of Vitamin E in a product should be the quantity of alpha tocopherol equivalents (ATE) and not of alpha tocopherol succinate (i.e. the source). For non-discrete dosage units only (e.g. topical creams, toothpastes, etc.), when the amount used is variable, the quantity may be expressed in terms of a percentage. When the ingredient is an extract, additional guidance is available in the Product Licensing guidance document. For homeopathic products, this is the dilution/potency of the ingredient. Only the most concentrated dilution should be included in this field. Refer to Chapter 4.3 of the Product Licensing guidance document for additional guidance.

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78	Indicate if the medicinal ingredient has been synthetically manufactured. A medicinal ingredient is considered to be synthetic for the purposes of NHPD if it is a semi-synthetic or synthetic duplicate of a NHP described in any of the items 2 to 5 of Schedule 1 of the Natural Health Products Regulations. If an ingredient is entirely produced by a chemical process from chemical compounds or partially chemically modified by a process that chemically changes a related natural starting material (i.e. an isolate or extract of a plant or a plant material, an alga, a fungus or an animal material), it is considered to be synthetic. An ingredient can be described as non-synthetic if it is obtained from a natural source material, is in a form found in nature, and has undergone only the most minimal processing (e.g. drying, grinding, powdering, chopping, encapsulating, etc.). Example: encapsulated powdered garlic. A medicinal ingredient can be considered to be from a natural source (thus also non-synthetic) if it is obtained via extraction, isolation and/or processing (e.g. boiling, steaming, etc.) of a plant, algal, fungal, bacterial, or animal material. However, the ingredient must have the same chemical identity as that in the source material. Ingredients found in nature that undergo chemical modification in order to increase their stability, absorbability, solubility, etc. (e.g. derivatives, salts, etc.) are considered to be synthetic. Example: Vitamin E (d-alpha-tocopherol) from soybean oil is non-synthetic (natural source), but d-alpha-tocopherol acetate is synthetic. Refer to the Evidence for Quality of Finished Natural Health Products guidance document for further information on synthetic duplicates and their specific requirements.
79	Indicate if the medicinal ingredient is derived from animal sources. If yes, the animal tissue form must be completed. This form can be found in Appendix 6 of the Product Licensing guidance document. A separate animal tissue form must be provided for each ingredient and each type of animal used (i.e. gelatin derived from pig skin and cow bones must be accompanied by two animal tissue forms, one for cow and one for pig). For additional information, refer to Chapter 5 of the Product Licensing guidance document.
80	The ingredient number corresponds to the ingredient number listed in Section 72 for easy referencing when preparing and reviewing the medicinal ingredients.

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81-83	There are different ways in which potency may be expressed. Potency may reflect the active constituent, a marker compound or the "activity" of the medicinal ingredient. Listing the potency on the product licence application is required only when a claim about the potency is to be on the label, or when it is required for a specific product (i.e. when the evidence supports the safety and efficacy of the product only with that standardized component). Amount (82): This is the amount of standardized component. It is usually expressed as a percentage. Constituent (83): This is the component to which the amount applies. For example: 0.3% hypericin Amount: 0.3% Constituent: hypericin When the extracted ingredient has been standardized and its potency is indicated, the crude material and ratio will not be required. For homeopathic medicines: The potency section of the form (amount & constituent) may be used to identify the weight or volume of a particular medicinal ingredient which is included in the container. e.g. Potency amount: 25 mg Potency constituent of D3 dilution Please note that the "homeopathic potency" of each ingredient must be filled out in the "quantity" section (77). Refer to Chapter 4.3 of the Product Licensing guidance document for additional guidance.
84	The source is the substance from which the medicinal ingredient was derived. When the process of isolation of a medicinal ingredient contains multiple "steps", one "step" back from the final medicinal ingredient may be sufficient in most cases. When a medicinal ingredient is stabilized as a derivative, this must be indicated in the source material field, as this stabilizing agent will be present in the final product. There may be multiple sources for a medicinal ingredient. If this is the case, list each source on a separate line. Refer to Chapter 4.3 of the Product Licensing guidance document for additional guidance.
85-89	Where the quantity per dosage unit provided in Section 77 is for an extracted ingredient, the ratio and quantity crude equivalent are required, except when the extracted ingredient is standardized (i.e. potency declared). Ratio (86): The ratio for extracts and tinctures should be denoted as crude material: preparation. Quantity crude equivalent (87): This is completed only in the case of an extract or tincture. It is the amount of crude ingredient used in the extract. Fresh/Dry (88-89): Indicate whether the quantity crude equivalent (87) is derived from fresh or dry original material by checking the appropriate box. Refer to Chapter 4.3 of the Product Licensing guidance document for additional guidance.

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90	For traditional claim submissions (Section 53), please insert the traditional method of preparation used to produce each medicinal ingredient (e.g. alcohol extraction, decoction, etc.). Please see the Evidence for Safety and Efficacy of Finished Natural Health Products guidance document for methods of preparation that are considered to be traditional. For non-traditional claim submissions, this area may be left blank.
91	If there is not sufficient room on the form for all the medicinal ingredients found in the product, please attach separate sheets, using the same format (72-90) and providing the same information as requested in the application. Please state the number of additional pages.
Block B	**PROPOSED NON-MEDICINAL INGREDIENT(S)**
	All non-medicinal ingredients and their purposes, found in the product must be listed as such within the Natural Health Products Ingredients Database (NHPID). Please note that some ingredients within the NHPID have associated limits or restrictions and these must also be considered when filing. If these ingredients or their purposes are not listed in the NHPID, applicants are responsible for submitting a request to NHPD to add these ingredients to the database before the application is filed. The application can only be filed once the ingredients are deemed acceptable and added to the database. For more information on how to request the addition of ingredients or other information to the NHPID, please refer to the NHPD Online Solution. Refer to Chapter 4.4 of the Product Licensing guidance document for additional guidance.
92	The ingredient number corresponds to the ingredient number listed in Section 97 for easy referencing when preparing and reviewing the non-medicinal ingredients.
93	Refer to the definition of proper name under the medicinal ingredient section, chapter 4.3 of the Product Licensing guidance document.
94	The common name of the non-medicinal ingredient is always required.
95	An excipient use or function is always required to be indicated for each non-medicinal ingredient. Acceptable excipient purposes include, but are not limited to, capsule shell, diluents, binders, lubricants, disintegrators, colouring agents and flavours.
96	If the ingredient is derived from animal sources, an animal tissue form must be completed. For additional information, refer to Chapter 5 of the Product Licensing guidance document.
97	The ingredient number corresponds to the ingredient number listed in Section 92 for easy referencing when preparing and reviewing the non-medicinal ingredients.
98	The standard (i.e. USP, EP, etc.) to which the non-medicinal ingredient conforms. If no mention is being made on the product label with reference to a particular standard or grade, this field may be left blank. Please note that some ingredients require a standard to be indicated, e.g. glycerin in non-capsule/table dosage forms.
99	The quantitative listing of the non-medicinal ingredient per dosage unit is only required if the non-medicinal ingredient has toxicity restrictions or could contribute to the product.
100	The origin of the non-medicinal ingredient should be listed as described above for medicinal ingredients (Section 84).

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Block C	**INGREDIENT(S) USED IN PROCESSING**
101	This question relates to whether or not animal tissue was used in the actual processing of the product (i.e. during the production process), not as a medicinal ingredient or non-medicinal ingredient. For example, the product may have come in contact with an animal-based substance during a stage of production, but this substance is not present in the final product. As per Chapter 5 of the *Product Licensing* guidance document, a completed Animal Tissue Form must be submitted if animal tissue is used in the processing of the product. A completed Animal Tissue Form must be included if animal tissue was used in the processing. If no animal tissue was used in the processing of the product, please indicate "no" as a response to this question.
Block D	**RECOMMENDED CONDITIONS OF USE**
102	A statement that indicates the intended beneficial effect of a NHP when used according to the recommended dose, duration of use and route of administration listed on the label. The recommended use or purpose is often called the health claim. Supporting references must be submitted to support each recommended use or purpose included on the Product Licence Application form. If supporting references are not provided to support the recommended use(s) or purpose(s), the application will be considered deficient. For additional information, refer to Chapter 4.5 of the Product Licensing guidance document.
103	The final physical form of the NHP that may be used by the consumer without requiring any further manufacturing. Only one dosage form will be allowed per application. The only exception is for Homeopathic products, which will be allowed to have more than one dosage form within a single product licence application. Please see the Evidence for Homeopathic Medicines guidance document for further details. NHPD's list of recognized dosage forms can be found in the NHPID. If a dosage form is not listed in the NHPID, the applicant must submit a NHPID Issue Form to have the dosage form included in the database.
104	The term sterile may be used when a product is processed in such a way that the finished product contains no viable microorganisms (as per United States Pharmacopoeia definition). Refer to Section IV of the Evidence for Quality of Finished Natural Health Products guidance document for further information on what is required to make the claim "sterile". If a product is indicated as sterile, this information must be indicated on the label. **All ophthalmic products (those applied to the eye) must be sterile.**
105	The route of administration is the method by which the NHP is to be delivered to the body. Routes of administration include, but are not limited to oral, buccal, dental, nasal and topical. As per Schedule 2 of the Natural Health Products Regulations, products to be administered by puncturing the dermis are not covered by the Natural Health Products Regulations. Only one route may be chosen. Please refer to Appendix 9 of the Product Licensing guidance document for route of administration. Please note for all products, including homeopathic products, one product licence will be issued per route of administration.

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106	The time frame in which a NHP can be consumed safely for its intended purpose (e.g. "May be used up to 7 days"). In some instances, direction will need to be given for a minimum time frame of consumption. In these cases, consumption for less than a recommended period of time may not result in beneficial effects. For example, the duration of use for a product may state, "Must be taken for a minimum of 4 weeks for beneficial effects to be demonstrated." However, there may not be a duration of use associated with certain products, such as products that are safe to be taken daily for prolonged periods (e.g. a multi-vitamin). In such cases, the duration of use field may be left blank. For homeopathic medicines, an appropriate duration of use statement is mandatory for homeopathic medicines with a specific recommended use or purpose but is optional for homeopathic medicines with a non-specific recommended use or purpose. Please see the Evidence for Homeopathic Medicines guidance document for further information.
107	Sub-population group: The group to which the NHP is targeted (may be more than one). If the NHP is intended to target multiple sub-population groups, all potential subpopulation groups should be listed on the product licence application along with the associated recommended dose. A sub-population group is any group that may require different dosing from the standard. For example, most NHPs are for adults, but seniors or children may take them at different doses.
108-110	The amount and dosage unit are used to express the quantity of the product to be taken at one time. When the dosage unit is a discrete (separate) dosage form, the recommended dose should be stated as the amount (number) of dosage units, such as the number of capsules, for example: No. of Dosage Units (110): 2 Dosage Unit (111): capsules When the dosage form is non-discrete (e.g. powder, liquid, etc.), the dosage unit may be expressed as teaspoon, tablespoon, mL, grams, scoop, dropper etc. Here are some examples of how the recommended dose may be expressed: Example #1 for non-discrete dosage form: No. of Dosage Units (110): 2 Dosage Unit (111): teaspoons (5 ml) Example #2 for non-discrete dosage form where the amount of the product used is variable: No. of Dosage Units (110): apply sparingly Dosage Unit (111): cream For additional examples, refer to Chapter 4.5 of the Product Licensing guidance document.
111	How often the product is to be taken in a given time or time interval (e.g. 3 tablets per day, 3 times per day, every 4 hours up to a maximum of …).
112	How the product should be taken. This may include time of administration, or administration with respect to food or drink (e.g. 2 capsules in the morning and 2 capsules in the evening or Take on a full stomach).

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113-115	If there are any cautions, warnings, adverse reactions and contraindications associated with the use of the NHP, they must be indicated. Cautions and Warnings (114): Cautions and warnings information identifies special care that must be exercised by the consumer prior to using the product to ensure safe and effective use of the NHP. Cautions and warning may also include information on the occurrence of serious potential hazards, and on particular conditions or situations in which a specific hazard may be anticipated. For example, "Consult your health care practitioner if you have known kidney problems or are taking diuretics". Contraindications (115): Contraindications deal with situations in which the NHP should not be used because the risk outweighs any potential benefit. For example, many products have not been proven safe in pregnant or breastfeeding women or may have a serious interaction with other medications. Known Adverse Reactions (116): Adverse reactions cover any noxious and unintended response to a NHP that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function. Examples include flushing, nausea, diarrhea and constipation.

	ATTESTATION
116	The attestation must be signed by the senior official of the company applying for the licence. If this name is different than that of the Senior Official identified in Part 1, Block B, then a Designated Party Authorization form must be included with this application.
117	Signature of the person listed as the authorized signing official in section 116.
118	The date on which the application was completed and signed.