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PRODUCT LICENSING GUIDANCE DOCUMENT

NATURAL HEALTH PRODUCTS DIRECTORATE

December 2006
Version 2.0

Canada

“Our mission is to help the people of Canada maintain and improve their health, while respecting individual choices and circumstances.”

Health Canada

“Our role is to ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.”

Natural Health Products Directorate

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OVERVIEW

All natural health products (NHPs) marketed for sale in Canada are subject to the *Food and Drugs Act*. The regulatory requirements specific to NHPs are outlined in the *Natural Health Products Regulations* (the Regulations).

This guidance document is intended to help product licence applicants interpret the terminology used in Section 5 of the Regulations and to complete a product licence application form and animal tissue form (if applicable).

Included in this guidance document are a description of the different submission types and their specific requirements. The product licence application form and all other relevant forms may be found on the Internet (see http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html).

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 new product number (NPN or DIN-HM in the case of homeopathic medicines) from the Natural Health Products Directorate (NHPD) as part of the product licence or it may also be used to apply for an amendment or provide a notification of changes for products that are already licensed.

Sections of the Regulations text appear in boxes in relevant locations throughout this guidance document. A complete version of the Regulations is available on the Internet (see http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/prodnatur/regs_cg2_e.html).

The information in this guidance document is based on the *Natural Health Products Regulations*, which were published in Canada Gazette, Part II, on June 18, 2003. The Regulations came into force on January 1, 2004.

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1.0 APPLICATIONS FOR PRODUCT LICENCES

The *Natural Health Products Regulations* (the Regulations) require individuals to obtain a **product licence** before they can sell a natural health product (NHP) in Canada.
[*Natural Health Products Regulations:* Part 1, Section 4]

To obtain a product licence, individuals must submit a **product licence application** to the Natural Health Products Directorate (NHPD). The application must include sufficient data to allow NHPD to evaluate the safety, quality and efficacy of the NHP when used according to the recommended conditions of use.
[*Natural Health Products Regulations*: Part 1, Section 5].

Upon request, applicants must also supply NHPD with **additional information or samples**.
[*Natural Health Products Regulations*: Part 1, Section 15]

2.0 TYPES OF PRODUCT LICENCE APPLICATIONS AND REQUIREMENTS

There are seven different types of applications that may be made for a product licence, each with its own submission requirements:

- Compendial (may have a traditional and/or non-traditional claim);
- Traditional Claim;
- Non-Traditional Claim;
- Homeopathic;
- TPD Category IV/Labelling Standard;
- Homeopathic DIN; and
- Transitional DIN.

The requirements for each of these types of applications are set out in Table 2.0 and **chapters 2.1 to 2.7** of this guidance document.

Multiple Flavours, Colours or Fragrances

Applicants for products with multiple possible flavours, fragrances or colours may submit a single product licence application listing all non-medicinal ingredients responsible for these attributes (flavours, colours and/or fragrances). **The only difference between these products must be the list of non-medicinal ingredients; all other information (e.g. dosage form, claim, medicinal ingredients, etc.) must be *exactly* the same.**

A single product licence application may also be submitted for multiple amounts of a single dosage form. For example, a product that is sold in bottles containing 90 or 180 capsules requires only one product licence application.

Table 2.0: Product Application Requirements

Requirements	Application Type								
	Compendial (NHPD Monograph)	Traditional Claim		Non-traditional Claim	Homeopathic		TPD Category IV/ Labelling Standard	Homeopathic DIN	Transitional DIN
		Regular stream	Pharmacopoeial stream		Specific Recommended use	Non-specific Recommended Use			
Product Licence Application form	✔	✔	✔	✔	✔	✔	✔	✔	✔
NHPD Label text	✔	✔	✔	✔	✔	✔	✔	✔A	✔A
Evidence Summary Report	Not applicable	✔	Not applicable	✔	Not applicable	Not applicable	Not Applicable	Not Applicable	Not applicable
References	B	C	H	D	E, F	F	G	Not applicable	Not applicable
Safety Summary Report	Not applicable	✔	✔	✔	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Animal Tissue form (if applicable)	✔	✔	✔	✔	✔	✔	✔	✔	✔
Quality Summary Report (including finished product specifications)	Not applicable	✔	✔	✔	✔	✔	✔	✔	✔

A - Also a copy of the most recent version of the label approved by the Therapeutic Products Directorate.
B - Attest to NHPD Monograph from the *Compendium of Monographs*.
C - Minimum of two traditional references (e.g. text books). Photocopy the relevant pages, including cover page
D - Minimum of two pieces of evidence to support product (e.g. full text journal article). Note that abstracts will not be accepted as key references; however they may be included in addition.
E – Photocopied and underlined evidence from at least one homeopathic reference to support the recommended use or purpose of each medicinal ingredient.
F – For each medicinal ingredient, a photocopy of the monograph from the pharmacopoeia to which the applicant attests.
G - Reference to the TPD Labelling Standard or Category IV monograph in cover letter
H - Only one approved pharmacopoeial reference (e.g. *Pharmacopoeia of the People's Republic of China*, or *State Drug Standard*) is required. Reference must meet criteria outlined in Appendix 7 of the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document.

2.1 Compendial Applications

Section 6 of the Regulations outlines the time limitation for a compendial product licence application.

> Part 1: PRODUCT LICENCES
> Sixty-Day Disposition
> Section 6
>
> **6.** (1) Subject to subsection (2), the Minister shall dispose of an application submitted under section 5 within 60 days after the day on which it is submitted if, in support of the application, the only information submitted by the applicant under paragraph 5(g) is that which is
>
> a) in the case of an application respecting a natural health product that has only one medicinal ingredient, contained in a monograph for that medicinal ingredient in the Compendium; and
>
> b) in the case of an application respecting a natural health product that has more than one medicinal ingredient, contained in a monograph for that combination of medicinal ingredients in the Compendium.
>
> (2) If the Minister requests that additional information or samples be submitted under section 15, the 60-day period referred to in subsection (1) does not include the number of days beginning on the day on which the request is made and ending on the day on which the additional information or samples are received.
> (3) For the purposes of this section, the Minister disposes of an application on the earlier of the day on which
>
> a) the licence is issued in accordance with section 7; and
>
> b) the applicant is sent a notice under subsection 9(1).

A compendial application must cite a monograph in NHPD's *Compendium of Monographs* – List of Published Monographs (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/index_e.html). The monographs provide information regarding the minimum quality requirements, the acceptable non-medicinal ingredients as well as support for the safety and the efficacy of the NHP. Several items on the product licence application need to parallel the monograph content exactly, including:

- medicinal ingredient proper name;
- medicinal ingredient common name;
- source of the medicinal ingredient;
- route of administration;
- dose;
- duration of use for the product (if any); and
- subpopulation group.

The remaining sections of the monograph may use a "statement to the effect of", which allows applicants to alter the wording, but not the meaning of these monograph elements:

- recommended use or purpose; and
- risk information.

When the application includes information that is different than that outlined in the *Compendium of Monographs* – List of Published Monographs, for the items listed above, it will no longer be reviewed within 60 calendar days. Note that the *Compendium of Monographs* also contains quality information. If any other information submitted is not identical to that on the monograph (e.g. the quality specifications are different, the dose does not reflect the specific monograph dose or range of doses on the monograph, etc.), the product will be evaluated through the non-compendial stream (i.e. as a non-traditional or traditional claim product, as applicable).

Combination Products

Note that if a product contains multiple ingredients that each have monographs, the application will only be considered to be compendial (and subject to the 60-day disposition) if the combination is included within one monograph. Products that contain ingredients that are combined and not allowed within one monograph will not be considered as compendial and thus not subject to the 60-day disposition.

The *Compendium of Monographs* outlines the requirements for review within the 60-day disposition. For further information, refer to the *Compendium of Monographs* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/index_e.html). For a list of NHPD Single Ingredient Monographs, see the list of published Single Ingredient Monographs at http://hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono_list_e.html, and for a list of NHPD Product Monographs, see the list of published Product Monographs at http://hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/product_mono_produit_e.html.

The submission requirements for a compendial application can be found in Table 2.0. For an example of a completed product licence application form refer to **Appendix 1** of this guidance document.

2.2 Traditional Claim Applications

The NHPD considers a traditional claim to encompass products that have been used within a cultural belief system or healing paradigm for at least 50 consecutive years. To make a traditional use claim, the method of preparation should be considered to be traditional and a minimum of two traditional references should be submitted supporting the recommended conditions of use or one acceptable Pharmacopoeial reference (e.g. *Pharmacopoeia of the People's Republic of China*, or *State Drug Standard*). When the application is for a combination product (i.e. more than one medicinal ingredient), traditional evidence should be submitted to support the use of this combination or the use of all of the components of the formulation within a single healing paradigm. Refer to the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html) for additional information on the safety and evidence requirements for products with a traditional claim. For an example of a completed product licence application form refer to **Appendix 2** of this guidance document.

2.3 Non-Traditional Claim Applications

For products for which applicants wish to make a non-traditional claim, scientific evidence supporting the safety and efficacy of the product according to the recommended conditions of use must be submitted. In cases of combination products that contain medicinal ingredients that have NHPD Monographs, applicants may cite the relevant NHPD monograph to support the safety and efficacy of that particular medicinal ingredient. For example, a product containing two medicinal ingredients with both ingredients having a NHPD monograph (i.e. glucosamine and chondroitin) would be considered a non-traditional application since a NHPD monograph for the combination is not found within the *Compendium of Monographs*. If a product does not meet the requirements of a NHPD monograph, Therapeutic Product Directorate (TPD) Category IV Monograph (TPD CAT IV) and a TPD Labelling Standard (LS), it can be submitted as an application as a non-traditional product. For example, a product containing only one medicinal ingredient that has a monograph (i.e. peppermint oil), but has a recommended dose higher than the dose listed in the *Compendium of Monographs* (i.e. the recommended dose according to the monograph is 0.05-0.2 mL, 3x/day but the dose is 0.5 mL, 3x/day) may be submitted as an application as a non-traditional product.

The submission requirements for a non-traditional claim application can be found in Table 2.0. However, as part of the Safety and Evidence Summary Report, a Combination Rationale should be provided if applicable. More information regarding the Safety and Evidence Summary Report and the requirements for a Combination Rationale can be found in the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document. For an example of a completed product licence application form refer to **Appendix 3** of this guidance document.

2.4 Homeopathic Applications

To be considered a Homeopathic Medicine, a product must meet two criteria. It should be:

- Manufactured from, or contain as medicinal ingredients, only those substances referenced in a homeopathic monograph in one of the following homeopathic pharmacopoeias, as they are amended from time to time:
  - *Homeopathic Pharmacopeia of the United States* (HPUS)
  - *Homöopathisches Arzneibuch* (HAB) (German Homeopathic Pharmacopoeia (GHP))
  - *Pharmacopée française* (French Pharmacopoeia) (PhF)
  - *European Pharmacopoeia* (Ph.Eur.)
  - *Encyclopedia of Homeopathic Pharmacopeia* (EHP)
- Prepared in accordance with the methods outlined in one of the above-mentioned homeopathic pharmacopoeias, as they are amended from time to time.

Homeopathic medicines may have a specific recommended use or purpose (i.e. claim to treat specific symptoms) or a non-specific recommended use or purpose (i.e. no specific claim is permitted). The submission requirements for a specific and non-specific recommended use or purpose for a homeopathic application can be found in Table 2.0.

The evidence package for a specific recommended use or purpose should include:

- for each medicinal ingredient, a photocopy of the monograph from the pharmacopoeia to which the applicant attests; and
- for homeopathic medicines with a specific use or purpose, photocopied and underlined evidence from at least one homeopathic reference to support the recommended use or purpose of each medicinal ingredient.

The evidence package for a non-specific recommended use or purpose should include:

- a photocopy of the monograph from the pharmacopoeia to which the applicant attests for each medicinal ingredient.

For further information on homeopathic medicines and for an example of a completed product licence application form for a homeopathic medicine refer to the *Evidence for Homeopathic Medicines* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html).

2.5 TPD Category IV/Labelling Standard Applications

Therapeutic Products Directorate (TPD) Category IV Monographs and Labelling Standards were originally prepared by the TPD in the 1990s as a tool to assist companies in applying for drug licences/DINs (Drug Identification Numbers) for low risk non-prescription drug products. TPD Labelling Standards were developed for drug products that had been on the market for a number of years and for which there was no need for companies to generate further evidence to support the safety and efficacy of the product.

Upon the introduction of the *Natural Health Product Regulations,* the ingredients outlined in the TPD Category IV Monographs and Labelling Standards were reviewed and some substances were reclassified as NHPs rather than drugs. Thus, products with a single or a combination of NHP ingredients are now governed by the *Natural Health Product Regulations* rather than the *Food and Drug Regulations*. Products containing both an NHP and a drug ingredient will be considered to be drugs, and will continue to be regulated by the TPD under the *Food and Drug Regulations*.

The NHPD is currently adapting the relevant TPD Category IV Monographs and Labelling Standards information into NHPD monographs. Once these monographs are incorporated into the NHPD *Compendium of Monographs*, all requirements for a Compendial submission will apply (refer to **chapter 2.1**).

As an interim approach for the review of product licence applications for products containing NHP ingredients currently set out in the TPD Category IV Monographs and Labelling Standards, a separate evaluation stream has been established to minimize delays.

Several items on the product licence application need to parallel the TPD Category IV Monograph or Labelling Standard exactly when an applicant wishes to reference a TPD Category IV Monograph or Labelling Standard that has not already been converted into an NHPD Monograph as evidence to support the safety and efficacy, including:

- medicinal ingredient(s) common name;

- dosage form;
- route of administration; and
- recommended dose for the product.

The remaining sections of the TPD Category IV Monographs and Labelling Standards may use a "statement to the effect of", which allows applicants to alter the wording, but not the meaning of these elements:

- recommended use or purpose;
- directions of use; and
- risk information.

Products that do not follow the guidelines set above (e.g. different recommended use/purpose, additional medicinal ingredients, etc.) will not be considered a TPD Category IV Monograph/Labelling standard submission and will instead be considered to be non-traditional products.

The TPD Category IV Monographs and Labelling Standards do not always capture all requirements outlined by the Regulations (e.g. source and proper name of medicinal ingredient(s), subpopulation group, etc.); however, these aspects of the product licence application must be provided and will be evaluated. Once the Category IV Monographs and Labelling Standards are converted into NHPD monographs, these deficiencies will have been addressed.

Not all of the **non**-medicinal ingredients (and their associated purposes) normally found in products that have TPD Category IV Monographs or Labelling Standards are captured in the current NHPD List of Acceptable Non-medicinal Ingredients and Non-medicinal Ingredient List of Purposes. For non-medicinal ingredients and purposes **not** listed as acceptable by the NHPD, the applicant should provide the name, purpose, quantity and associated safety information. The applicant should ensure that the common name of the non-medicinal ingredient is consistent with the International Nomenclature Cosmetic Ingredient (INCI) names found in the International Cosmetic Ingredient Dictionary and Handbook, if applicable. The NHPD will **not** accept non-medicinal ingredients listed in the Cosmetic Ingredient Hotlist (a list of prohibited or restricted substances developed by Health Canada) if the ingredient is not compliant with any of the requirements described in the Hotlist. The Cosmetic Ingredient Hotlist can be accessed on the Internet (http://www.hc-sc.gc.ca/cps-spc/person/cosmet/hotlist-liste_3_e.html).

The submission requirements for a TPD Category IV Monographs and Labelling Standards application can be found in Table 2.0; however, if a non-medicinal ingredient is not found on the NHPD's List of Acceptable Non-medicinal Ingredients, additional evidence should be provided to support the use of the ingredient (see the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html). For an example of a completed product licence application form refer to **Appendix 4** of this guidance document.

2.5.1 TPD Category IV Monographs and Labelling Standards for Vitamin and Mineral Applications

Applications referencing the *Dietary Vitamin Supplements and Dietary Mineral Supplements Category IV Monographs* and the *Vitamin Supplements and Mineral Supplements Labelling Standards* will be evaluated in a separate stream, provided that compliance with the following criteria on dosing and claims have been met **and** the non-medicinal ingredients used in the product are on the NHPD's List of Acceptable Non-medicinal Ingredients.

Dosing criteria: Until a multivitamin/mineral monograph is published, the NHPD will follow the dosing criteria established by the Dietary Reference Intakes and use the Tolerable Upper Intake Level (UL), which reflects the current scientific review of the data presently available. In the case where there is an UL established for the particular ingredient, the proposed dose should be lower or equal to that stated as the UL for that ingredient. Where no UL has been established, the maximum therapeutic dose set by the Therapeutic Products Directorate in the *Labelling Standard for Vitamin and Mineral Supplements* will be acceptable.

Claim criteria: In the case of individual vitamins and minerals, specific health claims should be made where there is evidence available to support specific uses for the particular vitamin or mineral. For example, Vitamin B12 "helps to produce red blood cells" would be considered a specific health claim. The claims of "dietary supplement", "vitamin/mineral supplement", "source of" and "for therapeutic use only" are considered generic, non-descriptive and non-informative, and therefore will not be acceptable on the label as the only claim for single ingredient products. In the case of combination products (containing two or more vitamins and/or minerals), supplement claims such as "vitamin supplement" or "mineral supplement or "vitamin/mineral supplement" or "multi-vitamin or multi-mineral" or "multi-vitamin/mineral" will be accepted. The claim "Factor in the maintenance of good health" will also be acceptable for combinations of vitamins and minerals. These non-specific claims may be acceptable as the sole claim; however, specific claims for individual vitamins and minerals contained in the product will also be accepted.

All of the submission requirements outlined above for TPD Category IV Monographs and Labelling Standards will apply for multivitamin and mineral products except that the Quality Summary Report will not be required (the applicant should attest to the quality requirements outlined in the Compendium of Monographs).

Applications referencing the Dietary Vitamin Supplements and Dietary Mineral Supplements Category IV Monographs and the Vitamin Supplements and Mineral Supplements Labelling Standards that follow all of the above requirements except for the fact that they contain non-medicinal ingredients that are not on the NHPD's List of Acceptable Non-medicinal Ingredients will not be evaluated within this special stream, but will be evaluated as regular TPD Category IV Monograph/Labelling Standard products and will thus require a Quality Summary Report.

2.6 Homeopathic DIN Applications

Homeopathic DINs are homeopathic medicines that have been previously issued a DIN (Drug Identification Number) by the TPD under the *Food and Drug Regulations*.

The DIN for the homeopathic medicines must not be cancelled by the TPD at the time of product transfer to NHPD to be considered a homeopathic DIN application. Since these products have already been approved by the TPD, additional homeopathic references are not required. If the product contains non-medicinal ingredients that are not listed in the NHPD's List of Acceptable Non-medicinal Ingredients (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html), the applicant should provide the name, purpose, quantity and associated safety information.

The submission requirements for a Homeopathic DIN application can be found in Table 2.0; however, if a non-medicinal ingredient is not found on the NHPD's List of Acceptable Non-medicinal Ingredients, additional evidence should be provided to support the use of the ingredient (see the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html). For more information on homeopathic medicines refer to the *Evidence for Homeopathic Medicines* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html).

2.7 Transitional DIN Product Applications

Transitional DIN products are NHPs that have been previously issued a DIN (Drug Identification Number) by the TPD under the *Food and Drug Regulations*.

The DIN must not have been cancelled by the TPD at the time of product transfer to NHPD to be considered a transitional DIN product. Since these products have already been approved by the TPD, complete Safety and Efficacy Summary Reports will not be required. However, the definition of non-medicinal ingredient as outlined by NHPD is different than that previously accepted by TPD and, thus, the non-medicinal ingredients (NMIs) currently being used may not meet the NHPD requirements. To meet the NHPD requirements, refer to the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document chapter on combination products and the List of Acceptable Non-Medicinal Ingredients (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html). In some cases, non-medicinal ingredients approved by TPD may be required to be listed as medicinal ingredients for the purposes of obtaining a Natural Product Number and a rationale for the combination will be required. In other cases, where the NMI has a legitimate non-medicinal ingredient purpose and the NMI is not listed in the NHPD's List of Acceptable Non-Medicinal Ingredients, the applicant should provide the name, purpose, quantity and associated safety information.

The submission requirements for a Transitional DIN application can be found in Table 2.0. however, if a non-medicinal ingredients is not found on the NHPD's List of Acceptable Non-medicinal Ingredients, additional evidence should be provided to support the use of the ingredient (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html). For an example of a completed product licence application form refer to **Appendix 5** of this guidance document.

3.0 HOW TO SUBMIT AN APPLICATION

The product licence application form may be downloaded from the Internet (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html). Completed product licence applications should be sent to:

Health Canada
Health Products and Food Branch
Natural Health Products Directorate
Bureau of Product Review and Assessment
Submission Management Division
Basement, Qualicum, Tower A
2936 Baseline Rd.
AL 3300C
Ottawa, ON K1A 0K9
Couriers: K2H 1B3

Applications for a product licence should be typed (handwritten submissions will not be accepted after January 1, 2006), submitted by mail/courier, and contain original signatures. The NHPD will not accept initial applications by fax or that are handwritten.

Upon receipt of your product licence application, the Submission Management Division will send out an acknowledgement letter by fax or by mail. This letter will state the submission number, file number and company code assigned to your application. These numbers should be referenced in all submission related correspondence. Once an application has been assigned a submission number, correspondence with the relevant processor at Level 1 may be mailed to the Health Products and Food Branch address (attention to the particular processor) or faxed to the number indicated in the acknowledgement letter.

Once a submission has been assigned to a submission coordinator at Level 2 (non-compendial applications) or a compendial assessment officer (compendial applications), all further correspondence, including responses to notices sent by the NHPD, should be addressed to the relevant submission coordinator or compendial assessment officer in the Submission Management Division at the address listed above or may be faxed to the Product Submission Coordination Unit or Monograph Management Unit (refer to fax number indicated in the correspondence from the respective units).

3.1 Document Presentation Recommendations

The following are only recommendations; however, they will assist the NHPD in processing your application quicker and provide easier document management during screening and assessment.

Provide two copies of the submission package for each application (exception: only one copy required for Compendial applications).

Cover Letters: A cover letter is strongly recommended, as it provides the NHPD with a good overview of the submission context. Any information that would be considered important to note

(i.e. the inclusion of a Letter of Access to a Master File, changes made for an amendment or notification) or may raise questions or concerns during the assessment should be addressed in this letter. A cover letter is highly recommended for Product Licence applications and Notifications, and required for an Amendment to a product licence according to Section 11 of the *Natural Health Products Regulations*.

Assembling a Product Licence Application, Amendment, or Notification: It is preferred that all documents are double hole punched at the top of the document and inserted on the right and left side of a white legal-size folder with fasteners in the following recommended order:

RIGHT SIDE	**LEFT SIDE**
1. Cover Letter	1. Product Licence Application Form
2. Letter of Access	2. Designated Party Authorization Form (if applicable)
	3. Animal Tissue Form (if applicable)
	4. NHPD Label Text
	5. TPD Label (if applicable)
	6. Quality Summary Report including finished product specifications (if applicable)
	7. Evidence Summary Report (if applicable)
	8. Safety Summary Report (if applicable)
	9. References (if applicable)

Depending on the product, some applications require several references to support the proposed recommended use or purpose. If the information contained on the left side of the folder exceeds one inch (1”) in thickness, the references may be provided in a separate accompanying binder. If binders are included with the application, each binder spine should show the following information:

- name of the applicant;
- proposed primary brand name of the product;
- volume number (e.g. vol. 1 of 3); and
- date of submission.

It is recommended that documents contained in the application or responses for additional information (i.e. Acknowledgement Notices, Processing Deficiency Notices, and Information Request Notices) should **not** be stapled, coiled, or bound.

3.2 How to Submit a General Submission Inquiry

Please contact the relevant processor, submission coordinator or compendial assessment officer for questions specific to a submission. For any inquiries relating to products that have not been assigned a submission number, the submission process, requirements and/or requests for product licence applications may be submitted by mail or fax to the address listed above, or by e-mail or phone at the coordinates listed below.

E-mail: NHPD_DPSN@hc-sc.gc.ca

Telephone:
Toll Free 1-888-774-5555
Ottawa Region (613) 948-8096

Fax: (613) 948-6810

4.0 PRODUCT LICENCE APPLICATION FORM

Section 5 of the *Natural Health Products Regulations* outlines the information required in a product licence application.

Part 1: PRODUCT LICENCES
Licence Application
Section 5

5. An application for a product licence shall be submitted to the Minister and shall contain the following information and documents:

a. the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant;

b. if the address submitted under paragraph (a) is not a Canadian address, the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant's representative in Canada to whom notices may be sent;

c. for each medicinal ingredient of the natural health product,

   i. its proper name and its common name,

   ii. its quantity per dosage unit,

   iii. its potency, if a representation relating to its potency is to be shown on any label of the natural health product,

   iv. a description of its source material, and

   v. a statement indicating whether it is synthetically manufactured.

d. a qualitative list of the non-medicinal ingredients that are proposed for the natural health product and for each ingredient listed, a statement that indicates the purpose of the ingredient;

e. each brand name under which the natural health product is proposed to be sold;

f. the recommended conditions of use for the natural health product;

g. information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use;

h. the text of each label that is proposed to be used in conjunction with the natural health product;

i. a copy of the specifications to which the natural health product will comply; and

j. one of the following attestations, namely,

   i. if the natural health product is imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3, or

   ii. if the natural health product is not imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, distributed and stored in accordance with requirements set out in Part 3.

The terms used in section 5 of the Regulations as they relate to the product licence application form are defined in the product licence application form and accompanying guide found on the internet at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html). It is recommended that this section be used with the product licence

application form and accompanying guide, since this portion of the guidance document expands upon terms used in different sections of the product licence application form.

An example of a completed product licence application form for a Compendial, Traditional, Non-traditional, TPD Labelling Standard/Category IV Monograph and Transitional DIN product can be found in Appendices 1-5, respectively of this guidance document. An example of a Homeopathic medicine product licence application form may be found in the *Evidence for Homeopathic Medicines* guidance document.

4.1 Referencing Submissions

This section refers to Block F (section 60) of the Product Licensing Application form and is used to indicate information provided in a previous submission that pertains to the new application. Applicants may wish to use the same quality, safety and/or efficacy summary reports to support multiple product licence applications (e.g. the summary reports may support multiple dosage forms, etc.). In this case, separate product licence application forms must be submitted for each dosage form, but only one of the product licence applications will contain all of the supporting evidence (i.e. safety and efficacy summary reports).

In order to cross reference information in another application, the minimum information provided on the Product Licence Application form in Part 2, Block F should be the submission number, file number, and summary report being referenced. It is also helpful to indicate in the cover letter that an application is cross referencing another application.

When an applicant wishes to reference another submission, he/she may 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 should reference the entire report and not submit any additional safety information). Therefore, parts of summary reports from multiple different submissions will not be allowed (i.e. an applicant cannot reference the one submission's safety information with regards to a medicinal ingredient and another submission for the safety of a second medicinal ingredient). An authorization letter is required if the applicant referencing the other application is not the same licensee/applicant indicated on the application.

In some circumstances a NHP Master File may be referenced by an applicant. A NHP Master File may be submitted (see Block G of the Product Licence Application form), when a company would like to submit proprietary information on behalf of another company (i.e. a manufacturer submitting proprietary manufacturing information on behalf of an applicant). An authorization letter is required, if the company referencing the NHP Master File is not the same company as the holder of the NHP Master File. For additional information on NHP Master Files, refer to the *Master File Procedures* guidance document.

An authorization letter may be required for either cross-referencing an application or NHP Master File. The authorization letter should be on official letter head and should be signed by the senior official of the company holding the application/NHP Master File being referenced.

Products that come in multiple possible flavours, fragrances or colours may be submitted as a single product licence application listing all non-medicinal ingredients responsible for these

attributes (flavour, colours and/or fragrance). All other information (i.e. dosage form, claim and medicinal ingredients) must be ***exactly*** the same.

4.2 Site Requirements for Product Licence Application

Part 1: PRODUCT LICENCES
Site Information
Section 22

22. (1) Subject to subsection (2), the licensee shall provide the Minister with the following information prior to commencing the sale of the natural health product:

a. in respect of each manufacturer, packager, labeller and importer of the natural health product

   i. the person's name, address and telephone number, and if applicable, the person's facsimile number and electronic mail address, and

   iii. if the person conducts the activity in Canada, the number assigned to the site licence issued in respect of that activity;

b. the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of each distributor of the natural health product;

c. the address of each building in which the natural health product is manufactured, packaged or labelled;

d. the address of each building in which the natural health product is stored for the purposes of importation or distribution; and

e. if the natural health product is imported, evidence demonstrating that the natural health product will be manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3.

f.

(2) If the natural health product is one in respect of which a drug identification number is assigned in accordance with subsection C.01.014.2 (1) of the Food and Drug Regulations and at the time the product licence is issued in respect of the natural health product it is already being sold, the licensee shall provide the information referred to in subsection (1) within 30 days after the day on which the product licence is issued.

The obligations in section 22 of the Regulations must be met before product licence holders may begin selling their products. On Page 3 of the Product licence application form, the applicant should, if this information is known/available at the time of applying for a product licence, 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 (section 62 of the Product Licence Application) and address (sections 64-68 of the form) of each company. For each company name and address provided, the associated activity/ activities must also be indicated (i.e. manufacturer, packager, labeller, distributor and/or importer) in section 63 of the form. If available, the site licence number assigned by the NHPD must also be provided. If there is insufficient space provided in the application form for all of the companies involved in the manufacturing, packaging, labelling, importing and distributing of the product, attach a separate sheet(s) (using the same format) and indicate in section 69 the number of additional pages attached for this purpose.

If site information cannot be provided with the application, leave this area blank. Refer to the *Site Licence Guidance Document* for details relating to site licensing. Distributors do not require a site licence and only companies with an address in Canada require a site licence from the NHPD.

In some cases, applicants will be applying for a product licence for products that have not yet been manufactured. In this case, if the site information is not known, this area may, once again, be left blank on the application; however, applicants are required to provide the NHPD with the relevant site information before commencing the sale of the product.

For Transitional DIN products that are presently on the market, the licensee must provide the relevant site information within 30 days of the product licence being issued.

4.3 Medicinal Ingredient Product Licence Application Requirements

4.3.1 Proper name

The proper name (Section 75 of the Product Licence Application) of each medicinal ingredient must be identified. One of the following names may be accepted as a proper name.

- When the ingredient is a vitamin, a name set out for that vitamin in item 3 of Schedule 1: biotin, folate, niacin, pantothenic acid, vitamin A, thiamine, riboflavin, vitamin B_6, vitamin B_{12}, and vitamins C, D and E. To maintain consistency, the proper name is the name included in the Dietary Reference Intakes publications, since this is the international standard.

- When the ingredient is a plant or a plant material, an alga, a fungus, a bacterium, an animal material or a probiotic (or an extract of a plant or a plant material, an alga, a fungus, a bacterium or animal material), the Latin name of its genus and, if any, its specific epithet.
  - The genus is the first part of the standard two-part (binomial) scientific name for an organism, often derived from the classical Greek or Latin name for the organism. Members of a genus are various species that are all descended from a common ancestor and that are more closely related to each other than to species of other genera in the same family.
  - The specific epithet is the second, generally descriptive, part of the standard two-part (binomial) scientific name for an organism. Together the genus and specific epithet comprise the name of a species. For example:
  - genus: Angelica
  - specific epithet: *archangelica*

- When the ingredient is other than one described in paragraphs a) and b), the chemical name of the ingredient.

An acceptable chemical name of an ingredient is any unambiguous chemical name provided by an authoritative reference such as the Merck Index, the United States Pharmacopeia Dictionary, etc., or a name determined using the International Union of Pure and Applied Chemistry (IUPAC) nomenclature system.

For example:

- proper name: L-Arginine or (2S)-2-Amino-5-{[amino(imino)methyl]amino}pentanoic acid
- common name: L-Arginine

For information on the proper names of homeopathic medicines, refer to the *Evidence for Homeopathic Medicines* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html).

The following Web sites may be helpful in identifying the proper name of ingredients:

For plants: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl?
http://www.itis.usda.gov/advanced_search.html
For animals: http://www.itis.usda.gov/advanced_search.html
For chemicals: http://chem.sis.nlm.nih.gov/chemidplus/
For enzymes: http://ca.expasy.org/enzyme/enzyme_details.html

4.3.2 Common Name

A common name (Section 76 of the Product Licence Application) is for any medicinal or non-medicinal ingredient contained in a NHP, the name by which it is commonly known and is designated in a scientific or technical reference. For example:

- proper name: *Zingiber officinale*
- common name: ginger

NHPD recognizes that there may be cases where the common name and proper name will be identical, for example: Calcium.

For information on the common names of homeopathic medicines, refer to the *Evidence for Homeopathic Medicines* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html).

Examples of proper and common names can be found in Table 4.3.2.1

Table 4.3.2.1: Examples of Proper and Common Names

Category of ingredient	Proper name	Common name	Source Material
Mineral	Calcium	Calcium	Calcium citrate
Vitamin	Thiamine	Vitamin B1	Thiamine Mononitrate
Animal material	*Squalus acanthias*	Shark cartilage	Cartilage of the spiny dogfish shark
Plant	*Panax quinquefolius*	American Ginseng	Root
Isolate	Glucosamine Sulphate	Glucosamine Sulphate	Glucosamine sulphate potassium chloride from shellfish exoskeleton
Enzyme	Papain	Papain	Papaya fruit

4.3.3 Quantity

Quantity (Section 77 of the Product Licence Application) is defined as the amount of medicinal ingredient *per dosage unit* (for example, per tablet). Each medicinal ingredient in the product must have a quantity associated with it, including a unit of measure (e.g. mg, gram, etc.). See Table 4.3.3.1, which lists particular units. 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 RRR-alpha-tocopherol and not of RRR-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, the quantity (section 77 of the Product Licence Application) is the amount of extracted medicinal ingredient contained in each dosage unit. When the medicinal ingredient is a non-standardized extract, the extract ratio and the quantity of crude equivalent (fresh or dry) must also be provided (see below for further definition of these terms), with the exception of fixed oils that have been removed by the purely physical means of pressing (e.g. flax oil, fish oil) since the published safety and efficacy evidence is based on the quantity of oil, not on the quantity of the source material. The extract ratio and quantity of crude equivalent will be required for all other pressed extracts such as succi or juices from fruit or stems (e.g. due to varying moisture content, the dose of *Echinacea purpurea* aerial parts' expressed juice has a recommended extract ratio of 2.5:1) unless a rationale for exception is provided based on the fact that the accompanying safety and efficacy evidence relates to the dose of pressed extract and not the dose of the source material. For standardized extracts, the extract ratio and quantity crude equivalent will not be required if standardization is accomplished by varying the extract ratio, or if the product dose is based on the quantity of the active ingredient to which the product was standardized (e.g. 12 to 50 mg 1-2x per day of sennosides A & B from senna leaf). However, if the product is standardized to a marker or only one of several possible active ingredients, such that the dose is based on the quantity of the herb and standardization is a measure of quality, then the extract ratio and quantity of crude equivalent are still required (e.g. 300 mg 3x per day of St. John’s Wort standardized to 4% hyperforin).

In the case of homeopathic medicines, the quantity is expressed as the dilution level of the medicinal ingredient. In other words, the “quantity” is the “homeopathic potency” (e.g. 12 CH). Refer to the *Evidence for Homeopathic Medic*ines guidance document for more details (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html).

Table 4.3.3.1: Quantity Unit Requirements

Class of Ingredient	**Quantity Unit**
Vitamins, Amino acids, Essential fatty acids, Minerals, Isolates	Milligrams, micrograms or grams (or other appropriate metric equivalent)
Probiotic	Colony forming units (cfu)
Homeopathic medicines	CH, C, X, D, M, CK, K, M, MK, LM, Q The unit should be listed in one of the acceptable homeopathic pharmacopoeia.

4.3.4 Synthetic

A medicinal ingredient is considered to be synthetic (Section 78 of the Product Licence Application) 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 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 its 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 should 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.

4.3.5 Potency

There are different ways in which potency (Sections 81-83 of the Product Licence Application) may be expressed. Potency may reflect the active constituent, a marker compound or the activity of the medicinal ingredient.

The potency may reflect the amount per dosage unit of the standardized component(s) that further characterizes the quantity of the ingredient. Potency may be expressed as a percentage or an amount per dosage unit of a standardized part of the medicinal ingredient. When expressing the potency of a standardized component, the amount (section 82) with an associated unit of measure and constituent (section 83) (i.e. the standardized substance) must be indicated. 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).

The term potency may also be used to describe the activity of a medicinal ingredient, including the activity of enzymes, herbs or vitamins (e.g. “IU” for Vitamin E, Vitamin D, Vitamin A, etc.). When the potency of a medicinal ingredient is referring to the activity of the medicinal ingredient, only the amount with an associated unit of measure, will be required (the potency constituent is not required – see Bromelain and Vitamin E examples in the following table). See Table 4.3.5.1 for examples of how to express the potency of a product.

Refer to the explanation of a standardized extract in section 85-89 under the definition of extract.

Table 4.3.5.1: Examples of How to Express Potency

Medicinal Ingredient		Medicinal Ingredient Quantity (per dosage unit)	Potency (per dosage unit)	
Proper Name	**Common Name**		**Amount**	**Constituent**
Echinacea purpurea	Echinacea	500 mg	2.0%	cichoric acid
Fish Oil	Fish Oil	1000 mg	180 mg 120 mg	Eicosapentaenoic acid (EPA) Decosahexaenoic acid (DHA)
Bromelain	Bromelain	300 mg	2000 GDU/gram (GDU-gelatin digesting units)	N/A
Vitamin E	d-alpha-tocopherol	15 mg	22.5 IU (IU-international units)	N/A
Cellulase	Cellulase	50 mg	50 FPU/g (FPU-filter paper units)	N/A

The term potency as used here is not applicable to homeopathic medicines. In the case of homeopathic medicines, this column may be left blank. As mentioned above, the homeopathic potency (e.g. 12CH) must be listed in the quantity per dosage unit field (section 77). Refer to the *Evidence for Homeopathic Medicines* guidance document for more details (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html).

For further information on the requirements of standardized products, refer to the *Evidence for Quality of Natural Health Products* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq_e.html).

4.3.6 Source Information

The source (Section 84 of the Product Licence Application) 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 in the form of a derivative[1], this *must* be indicated in the Source Information field, as this stabilizing agent will be present in the final product.

[1] **Derivative (including salt, ester, resinate, polymer or carrier form)** - some medicinal ingredients on Schedule 1 may only be used or are predominantly used in derivative, salt, ester, resinate, polymer or carrier form (i.e. the medicinal ingredient is "attached" to another molecule) in order to maintain the stability of the substance under environmental conditions such as moisture, light, temperature, acidity or alkalinity, etc., and/or to improve the absorption of the medicinal ingredient into the body. However, the derivative, salt, etc. **should yield the original Schedule 1 substance during digestion or absorption in the body** (i.e. calcium carbonate, a possible source of the medicinal ingredient Calcium, will break apart in the stomach to yield Calcium and Carbonate).

For details on source information for homeopathic medicines, refer to the *Evidence for Homeopathic Medicines* guidance document. (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html)

Animal material or extracts of animal material - The source material is the part of the animal used or "whole organism," if applicable, and the common name of the organism if not adequately captured in the medicinal ingredient name.

Bacteria (excluding probiotics) and other unicellular organisms - The source material is the strain (if available) or a description of the cell or organism (e.g. whole or disrupted cell, filaments, colonies, etc.)

Isolates (including essential fatty acids and amino acids) - The biological source of an isolates may or may not influence the pharmacological activity of the isolate. For example, the isolate Rutin, whether it is isolated from citrus peel or buckwheat seed has the same pharmacological activity, however, collagen isolated from a pig has a different pharmacological activity than collagen isolated from chicken. If the source of the isolate influences the pharmacological activity, the original biological material must be identified.

For example, where pharmacological activity is independent of the isolate and the isolate is a derivative, the source material should be indicated as the derivative with or without the original biological material (common name plus part of organism used). If there is no derivative, the source material should be presented as either the proper or common name (whichever is more appropriate) of the medicinal ingredient or the original biological material (common name plus part of organism used).

If the pharmacological activity is dependent on the source, the source material must be identified as the derivative, if present, plus the original biological material (common name plus part of the organism used) or if there is no derivative, the original biological source (common name plus part of the organism used) only must be indicated. For examples, please see Table 4.3.6.1.

Multicellular fungi or Algae or extracts of fungi or algae - The source material is the part of fungus or alga used (e.g. frond, blade, etc.) or "whole organism," if applicable, and the common name of the organism if not adequately captured in the medicinal ingredient name.

Plant or Plant Material or extracts of Plants or Plant Materials - The source material is the part of the plant used or whole plant, if applicable, and the common name of the organism if not adequately captured in the medicinal ingredient name.

Probiotics - The source is the strain number of the bacteria.

Synthetic duplicates - The source material is the derivative. If there is no derivative in the final product then the term "synthetic"[2] is to be entered in the source material field.

Vitamins and minerals - The source material is the derivative. If there is no derivative in the final product and the source is not synthetic, then the medicinal ingredient proper name may be

[2] Please note that if the source material is indicated as synthetic, the word "synthetic" does not have to appear on the label text. Refer to the definition of synthetic (section 78) which appears earlier in this guidance document.

repeated in the source material field or the original biological material may be stated (common name plus part of the organism used).

Table 4.3.6.1: Examples of Source Material Requirements

Ingredient Type	Medicinal Ingredient		Source Material
	Proper Name	Common Name	
Plant or Plant Material or extracts of Plant or Plant Materials	*Allium sativum*	Garlic	Bulb oil
	Berberis vulgaris	European Barberry	Bark of the root
Bacteria (excluding probiotics) and other unicellular organisms	*Spirulina platensis*	Spirulina	Cells
	Saccharomyces cerevisiae	Brewer's yeast	Whole cell
Probiotics	*Lactobacillus acidophilus*	Lactobacilli	T-134
Animal material or extracts of animal material	*Squalus acanthias*	Shark cartilage	Cartilage of the spiny dogfish shark
Multicellular fungi or Alga or extracts of fungi or algae	*Laminaria digitata*	Kelp or oarweed	Stipe and blade
	Grifola frondosa	Maitake mushroom	Fruiting body
	Lycoperdon perlatum	Puffball	Spores
Vitamins and minerals	Calcium	Calcium	Calcium carbonate or Calcium carbonate from coral
	Vitamin C	Ascorbic acid	Sodium ascorbate
	Vitamin D	Vitamin D3	Cholecalciferol
Synthetic duplicates	Melatonin	Melatonin	Synthetic
	Folate	Folic acid	Synthetic
Isolates (including essential fatty acids and amino acids)	Stem Bromelain	Bromelain	Pineapple stem

Ingredient Type	Medicinal Ingredient		Source Material
	Proper Name	Common Name	
Isolates (including essential fatty acids and amino acids)	Porcine pancreatic enzymes	Pancreatic enzymes	Pig pancreas
	Glucosamine sulphate	Glucosamine sulphate	Glucosamine sulphate potassium chloride or Glucosamine sulphate potassium chloride from shellfish exoskeleton
	Gamma-Linolenic acid	GLA	Gamma-Linolenic acid or Borage seed oil and Evening primrose seed oil
	Linoleic acid	Linoleic acid	Ethyl linoleate or Ethyl linoleate from safflower seed oil
	Rutin	Rutin	Rutin or citrus peel

	Melatonin	Melatonin	Melatonin or Cow pineal gland
	L-Lysine	Lysine	L-Lysine hydrochloride or L-Lysine hydrochloride from bacterial fermentation
	Type II Chicken Collagen	Collagen	Chicken sternum
	Hydrolyzed Type II Bovine Collagen	Hydrolyzed Collagen	Cow cartilage
Homeopathic medicines	Refer to the *Evidence for Homeopathic Medicines* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html)		

The NHPD recognizes that in some cases a single medicinal ingredient may contain multiple species or extracts/isolates of multiple species of plants, fungi, bacteria or animals and/or a mixture of ingredients in varying quantities. In this case, a single proper name may reflect a well known combination of ingredients as seen in a pharmacopoeia, scientific or traditional reference and the source material may be indicated as the common names (and/or proper names if required for safety and efficacy evaluation), of the organisms it is derived from plus the parts of the organisms used. When multiple sources are present it is suggested (although not required), that the sources be listed in descending order of content. For example:

Medicinal Ingredient		**Source Material**
Proper Name	**Common Name**	
Fish Oil	Fish Oil	Anchovy, sardine and mackerel oil
Massa fermentata	Medicated leaven	*Prunus armeniaca* kernel *Artemisia annua* whole plant *Polygonum hydropiper* whole plant *Xanthium sibiricum* whole plant *Vigna umbellata* seed *Triticum aestivum* bran

During the evaluation process, it may be required to provide the approximate content of each plant or animal material in the mixture and/or the proper names (Latin binomials) of the most common species used.

4.3.7 Extract

An extract (Section 85-89 of the Product Licence Application) is prepared by treating (e.g. soaking in alcohol, steam distilling, etc.) a plant, plant material, alga, bacterium, fungus, animal material or other NHP to remove a specific group of chemicals (e.g. biomarkers or active compounds). Alternatively, an extract may be removed from the original starting material by purely physical means (e.g. cold pressing, hot pressing, etc.).

An extract may be standardized or non-standardized in the finished product. A standardized extract is manufactured in such a way as to guarantee an amount of certain chemicals that are bioactive constituent(s) or marker(s) or to guarantee a certain level of activity (i.e. to guarantee a potency – see sections 81-83 for the definition of the word potency).

Refer to the *Evidence for Quality of Finished Natural Health Products* guidance document for more details on extraction processes (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq_e.html).

When the ingredient is an extract, the quantity (section 77 of the Product Licence Application) is the amount of extracted medicinal ingredient contained in each dosage unit. When the medicinal ingredient is a non-standardized extract, the extract ratio and the quantity crude equivalent (fresh or dry) must also be provided (see below for a further definition of these terms). The extract ratio and quantity crude equivalent will not be required for extracts that have been removed by purely physical means (e.g. pressing, etc.) or for standardized extracts as these values may vary in order to ensure a certain level of the standardized component.

Extraction Ratio (Section 86 of the Product Licence Application). (for non-standardized extracts). The extraction ratio is always expressed as the quantity of crude material (fresh or dry) to extract, regardless of whether it is a liquid or a solid. For example, a tincture (liquid) ratio of 1:5 means that 1 g of crude dried material was used to prepare 5 ml of extract. In a solid extract, a ratio of 5:1 means that 5 g of crude dried material was used to prepare 1 g of extract.

Quantity Crude Equivalent (Sections 87-89 of the Product Licence Application). (for non-standardized extracts). The quantity crude equivalent is the amount of crude dried or fresh material (amount of original material) from which the ingredient was extracted (per dosage unit). When stating the quantity crude equivalent (section 87), it must be indicated whether the amount of the original starting material being referred to is the fresh (section 88) or dry (section 89) amount.

Some examples include:

Solid extraction:

1 gram (crude dry material) of *Curcuma longa* was treated with ethanol and dried to produce 250 mg of extract.

On the PLA form:

Quantity of *Curcuma longa* extract per dosage unit – 250 mg
Extract ratio – 4:1
Quantity crude equivalent (dry) – 1000 mg

Single ingredient tincture:

1 gram of dry *Echinacea purpurea* dissolved in 5 mL of ethanol

On the PLA form:

Quantity of *Echinacea purpurea* per dosage unit – 5 mL
Extract ratio – 1:5
Quantity crude equivalent (dry) – 1 g

For multiple ingredient tinctures that are prepared by mixing multiple single ingredient tinctures prepared at different extraction ratios:

Tincture A - 1 gram of dry *Crataegus monogyna* added to 5 mL of ethanol (extraction ratio 1:5)
Tincture B - 2 grams of dry *Atractylodes macrocephala* added to 8 mL of ethanol (extraction ratio 1:4)

For the final product (Tincture C), 1 mL of Tincture A was mixed with 1 mL of Tincture B to get a total of 2 mL in the final dosage unit

For A: 1 gram/5 mL = 0.2 grams/1 mL For B: 2 grams/ 8 mL = 0.25 grams/1 mL

In the final product, Tincture C (total 2 mL) contains:

0.2 grams of A per dosage unit
0.25 grams of B per dosage unit

Extraction ratio for A (*Crataegus monogyna*) in the final product is 1:10
(equivalent of 0.2:2)
With a quantity crude equivalent (dry) of 0.2 grams

Extraction Ratio for B (*Atractylodes macrocephala*) in the final product is 1:8
(equivalent of 0.25:2)
With a quantity crude equivalent (dry) of 0.25 grams

4.4 Non-Medicinal Ingredient Product Licence Application Requirements

Part 4, Block B of the Product Licence Application form lists the requirements for a non-medicinal ingredient. A non-medicinal ingredient is any substance added to a NHP to confer suitable consistency or form to the medicinal ingredients. Non-medicinal ingredients may include, but are not limited to, capsule components, diluents, binders, lubricants, disintegrators, colouring agents and flavours. A list of acceptable non-medicinal ingredient purposes can be found in **Appendix 7** - Non-medicinal Ingredient List of Purposes. This list is not comprehensive and other possible purposes may be accepted upon appropriate evaluation.

The NHPD has developed a list of non-medicinal ingredients that are generally regarded to be of minimal toxicological concern (refer to the acceptable Non-medicinal Ingredients List which appears as an appendix to the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document). When used under the limitations outlined in this list, these ingredients are considered to be safe, and will not require further assessment by NHPD.

Other types of non-medicinal ingredients may require safety assessment by NHPD. Applicants are required to submit additional information (e.g. quantity per dosage unit, source information, etc.) with their initial product licence application for non-medicinal ingredients not found on the NHPD's acceptable list, so as to not delay the assessment process. Refer to the Non-medicinal Ingredients section in the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document for further information on the requirements for non-medicinal ingredients.

Unless the mixture is identified by a common name on the NHPD's List of Acceptable Non-medicinal Ingredients, the components of mixtures, should be identified as individual non-medicinal ingredients. For ingredient mixtures that are considered to be proprietary (e.g. some fragrances, flavours, etc.), the common name must be indicated (e.g. green apple #4 fragrance) on the product licence application form and the applicant may be required to request from the manufacturer of the proprietary mixture that a Master file be submitted directly to the NHPD outlining the specific ingredients. In some cases when a mixture is used, a general term only will be required for the label text (e.g. fragrance).

For flavours and colorants, the applicant will be required to designate the type of flavour (i.e. cherry, lemon, etc.), any colorants used, and whether the flavour or colorant is artificial or natural. A proprietary flavour mix that contains any artificial part will be considered to be artificial. The label, however, will not be required to contain the word "artificial".

Purpose (Section 95 of the Product Licence Application). An excipient use or function is 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. A list of acceptable non-medicinal ingredient purposes can be found in **Appendix 7**. This list is not comprehensive and other possible purposes may be accepted upon appropriate evaluation.

4.5 Recommended Conditions of Use

Recommended use or purpose (Section 102 of the Product Licence Application). Applicants are required to submit 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.

NHPD's standards of evidence framework outlines two categories of claims: traditional use claims and non-traditional use claims. Within these two categories, and depending on the evidence submitted, the applicant may choose the appropriate recommended use or purposes. For example, the applicant may decide to have a traditional use claim for the treatment of a disease or health-related condition.

NHPD's standards of evidence framework lists the types of recommended uses or purposes (health claims) permitted, based on the credibility, strength and quality of evidence submitted with the application that supports the claim. Three types of claims are permitted, as follows:

- **Treatment claims:** these relate to the diagnosis, treatment or mitigation, or prevention of a disease, disorder or abnormal physical state, or its symptoms in humans.
- **Risk reduction claims:** these claims describe the relationship between using a medicinal ingredient and reducing the risk of developing a chronic disease or abnormal physiological state, by significantly altering a major risk factor or factors recognized to be involved in its development.
- **Structure-function claims:** these claims describe the effect of a medicinal ingredient on a structure or physiological function in the human body, or a product's support of an anatomical or physiological function. This category includes claims of maintaining or promoting health.

The NHPD also allows applicants to make a non-specific claim, depending on the evidence available. These claims take the form of a broad statement that the product will promote overall health.

Refer to the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html) for further information on claims. Refer to the *Evidence for Homeopathic Medicines* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html) for details regarding claims made on homeopathic medicines.

Amount and Dosage Unit (Sections 108-110 of the Product Licence Application).

The number of dosage units (section 109) and the dosage unit (section 110) are used to express the quantity of the product to be taken **at one time**. For examples specific to homeopathic medicines refer to the *Evidence for Homeopathic Medicines* guidance document (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html).

When the dosage unit is a **discrete** (separate) dosage form, the recommended dose should be stated as the number of dosage units, such as the number of capsules, for example:

The medicinal ingredient quantity (section 77) is expressed as the amount per capsule and the dose is 2 capsules, 3 times per day for an adult:

Subpopulation Group	Amount to be taken at one time		Frequency	Directions of Use
	Number of Dosage units	Dosage Unit		
Adults	2	Capsule	3 times daily	Take 2 capsules 3 times daily with meals

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:

The medicinal ingredient quantity (section 77) is expressed as the amount per teaspoon and the dose is 1½ teaspoons per day for an adult and ¼ teaspoons twice per day for children 6-12:

Subpopulation Group	Amount to be taken at one time		Frequency	Directions of Use
	Number of Dosage units	Dosage Unit		
Adults	1 ½	Teaspoon	Once daily	Take 1 ½ teaspoons daily on an empty stomach
Children 6-12	¼	Teaspoon	Twice daily	Take ¼ teaspoon twice daily on an empty stomach

The medicinal ingredient quantity (section 77) is expressed per drop and the dosage is 20-30 drops per day for adults:

Subpopulation Group	Amount to be taken at one time		Frequency	Directions of Use
	Number of Dosage units	Dosage Unit		
Adults	20-30	Drops	Daily	Take 20-30 drops daily on an empty stomach

Alternatively, if the medicinal ingredient quantity (section 77) is expressed as the amount in 10 drops, the recommended dose may be expressed as follows:

Subpopulation Group	Amount to be taken at one time		Frequency	Directions of Use
	Number of Dosage units	Dosage Unit		
Adults	2-3	10 drops	Daily	Take 20-30 drops daily on an empty stomach OR Take 2-3 of a 10 drop dose daily on an empty stomach

If the medicinal ingredient quantity (section 77) is expressed as the amount per mL and the dose was 2 mL (1 mL=30 drops):

Subpopulation Group	Amount to be taken at one time		Frequency	Directions of Use
	Number of Dosage units	Dosage Unit		
Adults	2	mL (=30 drops)	Daily	Take 2 mL daily (60 drops) with food

If the medicinal ingredient quantity (section 77) is expressed as the amount in ½ dropper and the dose was ½-1 dropper per day:

Subpopulation Group	Amount to be taken at one time		Frequency	Directions of Use
	Number of Dosage units	Dosage Unit		
Adults	1-2	½ dropper	Daily	Take one to two ½ dropper daily before dinner OR Take ½-1 dropper full daily before dinner

Alternately, the amount of medicinal ingredient may be expressed as the amount in one dropper (section 77) with the dose ½-1 dropper daily:

Subpopulation Group	Amount to be taken at one time		Frequency	Directions of Use
	Number of Dosage units	Dosage Unit		
Adults	½-1	dropper	Daily	Take ½-1 dropper daily after meals or as directed by a health care practitioner

For **non-discrete** dosage forms such as ointment and creams, where the **amount of the product used is variable**, the medicinal ingredient quantity should be expressed as a percentage and the recommended dose amount may be stated as “apply sparingly”, “apply liberally” or “apply as needed”. In this case, the dosage unit would be equivalent to the dosage form (e.g. cream, ointment, etc.). For example:

Subpopulation Group	Amount to be taken at one time		Frequency	Directions of Use
	Number of Dosage units	Dosage Unit		
Adults	Apply sparingly	Cream	Maximum 3 times daily	Apply sparingly to affected area up to 3x per day.

For toothpastes, the medicinal ingredient amount may be expressed as a percentage and the amount may be expressed as follows:

Subpopulation Group	Amount to be taken at one time		Frequency	Directions of Use
	Number of Dosage units	Dosage Unit		
Adults and children over 6 or N/A	Cover toothbrush	Dentifrice	N/A	Brush teeth thoroughly
Children under 6	Pea-sized amount	Dentifrice	N/A	Brush teeth thoroughly

5.0 ANIMAL TISSUE FORM

An animal tissue form may be required for the following types of ingredients:

- medicinal ingredient;
- non-medicinal ingredient; or
- an ingredient used in processing (i.e. not present in the final product).

A **separate** animal tissue form should be provided for:

- **each** ingredient (i.e. medicinal, non-medicinal, or an ingredient used in processing);
- **each** type of process; and
- **each** type of animal (i.e. mammal, bird or crustacean).

For animal tissue that is derived from a mammal, bird or crustacean (e.g. cattle, poultry, and crayfish), a single animal tissue form should be submitted for **each** animal type (genus level of classification). For example, a medicinal ingredient containing animal tissue from both cattle and poultry would require **two** separate animal tissue forms (i.e. one form for the cattle source, and one form for the poultry source). For animal tissue that is not derived from a mammal, bird or crustacean, including insects, fish, reptiles, etc. a single animal tissue form may be submitted for multiple closely related animals used in a single medicinal ingredient. For example, the medicinal ingredient fish oil derived from sardines, anchovy and mackerel may be accompanied by a single animal tissue form that includes sardines, mackerel and anchovy.

Note that specified risk materials (SRMs) are not permitted to be used for manufacturing and/or in the processing of NHPs. SRMs are defined in the *Food and Drugs Regulations* as the skull, brain, trigeminal ganglia (nerves attached to the brain), eyes, tonsils, spinal cord and dorsal root ganglia (nerves attached to the spinal cord), of cattle aged 30 months or older AND the distal ileum (part of small intestine) of cattle of all ages.

Table 5.0 Examples of Animal Tissue Form Requirements

Material	How the material might be used	Animal Tissue Form Required?
Sheep wool	Starting material for Vitamin D	Yes
Duck feather	Starting material for amino acid	Yes
Human hair	Starting material for amino acid	Yes
Human placenta	Traditional medicine	Yes
Glands and organs of cattle, pig, sheep, etc.	Medicinal ingredient	Yes
Insects	Colouring agent	Yes
Oyster shell	Source of Calcium	Yes
Milk	Source of Lactose	Yes
Bee saliva/Royal jelly	Royal jelly	Yes

Material	How the material might be used	Animal Tissue Form Required?
Bee pollen	Bee pollen	No
Honey	Medicinal ingredient	No
Beeswax	Non-medicinal ingredient	No
Propolis	Medicinal ingredient	No
Bacteria*	Probiotic	No
Yeast	Medicinal ingredient	No
* Bacteria are not animal tissue; however, if the bacteria are cultured from or using animal tissue (e.g. fetal bovine serum culture nutrient) this animal tissue should be indicated as animal tissue used in the processing of the product (answer 'yes' to the question "Was **animal tissue used in the processing** of this product but not present in the final product" (Part 4, Block C, section 101 of the Product Licence Application form) and an animal tissue form should be provided.		

5.1 Instructions for Completing the Animal Tissue Form

The information supplied by this form will be used to determine the risk of transmission of animal born disease. **If there are any changes to the source or the type of animal sourced material, an application for a product licence amendment must be submitted.**

Ingredient derived from animal tissue. Indicate the name of the medicinal or non-medicinal ingredient that uses animal tissue as it is seen on the product licence application form. When the animal tissue was used in the processing only, indicate the animal substance here. Only one ingredient may be entered per animal tissue form.

Used as. Indicate if the animal tissue indicated is used as an **ingredient** (includes either medicinal or non-medicinal ingredients) or if it is used in the **processing** of the product (i.e. not found in the final product).

Animal species. Indicate the common name of the type of animal used. For each different type of animal outlined on the animal tissue form, a separate animal tissue form should be submitted. When the type of animal is different from those types mentioned (i.e. not cattle, deer, elk, sheep, goat, pig, poultry or crustacean) and is not a bird or mammal, a single animal tissue form may be sufficient to encompass multiple similar species. For example, one animal tissue form may be submitted for multiple species of fish (e.g. salmon, tuna, etc.).

Animal tissue used. Indicate the part of the animal used.

What is (or will be) the age of the animals used. The age range of the animals used should be indicated only when the animal species used in Question 3 of the animal tissue form is indicated as cattle, goat, sheep, deer or elk,. If after appropriate inquiry, the age of the animals used is unable to be determined, submit a justification as to why the age of the animals is unavailable and a scientific explanation as to why this product does not present a risk for transmission of animal borne disease.

Country/countries from which the animals originated (or will originate). The country of origin of the animals used should be indicated only when the animal species used in Question 3 of the animal tissue form is indicated as cattle, goat, sheep, deer or elk. If, after appropriate inquiry, the country of origin of the animal used cannot be determined, submit a justification as to why this information is unavailable and a scientific explanation as to why this product does not present a risk for transmission of animal-borne disease.

Signing Authority. The animal tissue form should be signed and dated by the senior official of the company applying for the licence. If this name is different than the one indicated on page 1 (part 1, block B) of the product licence application form, the application should include a Designated Party Authorization form, allowing the designated person to sign for the senior official. Refer to the internet (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html) for a copy of the Designated Party Authorization form.

APPENDIX 1: EXAMPLE OF A COMPENDIAL APPLICATION

Health Canada / Santé Canada

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* Herbs and Vitamins Inc.			5. Company Code (If known)
6. Address: Street/Suite/PO Box* 123 Union Street			
7. City – Town* Ottawa	9. Province – State* Ontario	8. Country* Canada	10. Postal/ZIP Code* K2H 1X3

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

11. Name ■ Mr. □ Ms. □ Dr. Surname* Lalonde Given Name* Guy		12. Title CEO	13. Language preferred: ■ English □ French
14. Company Name (* if different from Applicant/Licensee) Herbs Are Us Inc.			**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.* (613) 555-1234	Ext. 101	22. Fax No. (613) 555-4321	23. E-mail g_lalonde@herbsvitamins.com

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* Thompson Given Name* Gary	Regulatory Affairs Associate	
28. Company Name (*if different from Applicant/Licensee) Herbs Are Us Inc.		**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.* (613) 555-1234	Ext. 201	36. Fax No. (613) 555-4321	37. E-mail g_thompson@herbsvitamins.com

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)

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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.

Number of Volumes: 1

			Volume #
■ Product licence application form	□ Animal tissue form(s)	#: _____	_____
□ Additional pages for Product Information	□ Designated Party Authorization form:		_____
□ Additional pages for Site Information	■ Label Text	#: 2	1
□ Evidence Summary Report:	□ TPD Label Text (Transitional DIN or Homeopathic DIN)	#: _____	_____
□ Safety Summary Report:	□ Quality Summary Report:		_____
	■ Other, Claim Evidence: Monograph - Alfalfa		1

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: _____

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 3 – SITE INFORMATION

62. Company Name Herbs and Vitamins Inc.			63. ■ Manufacturer SL# 312346 ■ Packager SL# 312346 ■ Labeller SL# 312346 ☐ Importer SL# ___ ■ Distributor
64. Number, Street – Suite – PO Box 123 Union Street			
65. City Ottawa			
66. Province – State Ontario	67. Country Canada	68. Postal Code – Zip Code K2H 1X3	
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: ___			

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

70. Primary Brand Name* Dr. Smith's Alfalfa

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.		Alfalfa	Mar 5/04	*Medicago sativa* L.	Alfalfa	10 g		X		X
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.			Aerial parts					
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								

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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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.		Calcium Phosphate Dibasic Dihydrate	Diluent		X
2.		Magnesium stearate	Lubricant		X
3.		Cellulose, Microcrystalline	Binder		X
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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

D. – RECOMMENDED CONDITIONS OF USE

102. Recommended Use or Purpose*
Traditionally used as a digestive tonic.

103. Dosage Form (one only)*	104. Sterile* □ Yes ■ No	105. Route of Administration*
Caplet		Oral

106. Duration of Use (if any)
For prolonged use, consult a health care practitioner.

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.)		
Adult	1	Caplet	3 times per day	

Risk Information

113. Cautions and Warnings*

Consult a health care practitioner prior to use if you are taking blood thinners, if you are taking birth control medication or if you are undergoing hormone replacement therapy.

Avoid prolonged exposure to sources of ultraviolet radiation (e.g. sunlight, black light, tanning salons or other tanning devices).

114. Contraindications*

Do not use if you have a history of systemic lupus erythematosus, if you are taking corticosteroids, if you are taking cyclosporine, or if you are pregnant or breastfeeding.

115. Known Adverse Reactions*

Not applicable.

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*
Guy Lalonde	*Guy Lalonde*	2 0 0 6 0 9 2 2

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.

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

APPENDIX 2: EXAMPLE OF A TRADITIONAL APPLICATION

Health Canada / Santé Canada

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* Chinese Herbs Inc.			5. Company Code (If known)
6. Address: Street/Suite/PO Box* 123 St. Joseph Blvd, Suite 1000			
7. City – Town* Toronto	9. Province – State* Ontario	8. Country* Canada	10. Postal/ZIP Code* M1X 2X8

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

11. Name ■ Mr. □ Ms. □ Dr. Surname* Lee Given Name* John		12. Title President	13. Language preferred: ■ English □ French
14. Company Name (* if different from Applicant/Licensee) Chinese Herbs Inc.			**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.* (416) 555-1234	Ext. 101	22. Fax No. (416) 555-1235	23. E-mail jlee@chineseherbs.com

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* Jones Given Name* David		Regulatory Affairs Consultant	
28. Company Name (*if different from Applicant/Licensee) Jone's Regulatory Affairs Services			**29. Address same as "A" □**
30. Street/Suite/PO Box* 123 Naturelle Rd.			
31. City – Town* Toronto	33. Province – State* Ontario	32. Country* Canada	34. Postal/Zip Code* M2H 2X9

35. Telephone No.* (416) 555-4321	Ext. 201	36. Fax No. (613) 555-4320	37. E-mail david_jones@jonemail.com

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)

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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

5. 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: 1	□ Animal tissue form(s)	#: _____	_____
■ Product licence application form	□ Designated Party Authorization form:		_____
□ Additional pages for Product Information	■ Label Text	#: 2	1
□ Additional pages for Site Information	□ TPD Label Text (Transitional DIN or Homeopathic DIN)	#: _____	_____
□ Evidence Summary Report:	■ Quality Summary Report:		1
■ Safety Summary Report:	■ Other, Claim Evidence: Pharmacopoeia of the People's Republic of China		1

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: _____

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 3 – SITE INFORMATION

62. Company Name Chinese Herbs Inc.			63. ☐ Manufacturer SL# ________ ☐ Packager SL# ________ ■ Labeller SL# __312346__ ■ Importer SL# __312346__ ■ Distributor
64. Number, Street – Suite – PO Box 123 St. Joseph Blvd, Suite 1000			
65. City Toronto			
66. Province – State Ontario	67. Country Canada	68. Postal Code – Zip Code M1X 2X8	
62. Company Name Trading Company			63. ■ Manufacturer SL# not required ■ Packager SL# not required ☐ Labeller SL# ________ ☐ Importer SL# ________ ☐ Distributor
64. Number, Street – Suite – PO Box 15 North Road of Dong San Huan, Chao Yang District			
65. City Shenyang			
66. Province – State Liaoning	67. Country China	68. Postal Code – Zip Code 100001	
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: __________			

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

70. Primary Brand Name* Chinese Lung Remedy

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.				*Ephedra sinica*	Ma huang	35 mg		X		X
2.				*Citrus reticulata*	Mandarin orange	24 mg		X		X
3.				*Platycodon grandiflorus*	Balloon flower	24 mg		X		X
4.				*Pinellia ternata*	Ban xia	70 mg		X		X
5.				*Schisandra chinensis*	Magnolia vine	15 mg		X		X
6.				*Polygala tenuifolia*	Chinese senega	15 mg		X		X
7.				*Fritillaria cirrhosa*	Chuan bei mu	25 mg		X		X
8.				*Glycyrrhiza uralensis*	Chinese licorice	15 mg		X		X
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.	2.1 mg	Ephedrine hydrochloride	Stem	3:1	105 mg			Traditional
2.			Peel	4:1	96 mg			Traditional
3.			Root	4:1	96 mg			Traditional
4.			Rhizome					Traditional
5.			Fruit	5:1	75 mg			Traditional
6.			Root	5:1	75 mg			Traditional
7.			Bulb					Traditional
8.			root	3:1	45 mg			Traditional
9.								
10.								
11.								
12.								

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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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.		Corn starch	Binder		X
2.		Sugar	Sweetening agent		X
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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

D. – RECOMMENDED CONDITIONS OF USE

102. Recommended Use or Purpose*
Traditional Chinese medicine to restore Lung Qi and reduce phlegm.

103. Dosage Form (one only)*	104. Sterile*	105. Route of Administration*
Tablet	□ Yes ■ No	Oral

106. Duration of Use (if any)
For prolonged use, consult a health care practitioner.

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.)		
Adult	3	Tablets	3 times per day	Do not take more than 9 tablets/day.

Risk Information

113. Cautions and Warnings*
Discontinue use and consult a health care practitioner if symptoms persist. Consult a health care practitioner, if you are taking other medications, if you have hypertension or heart disease, or if you spit blood, your tongue is red or you have hot phlegm.

Discontinue use if you experience prolonged gastrointestinal distress.

114. Contraindications*
Do not use if you are pregnant or breastfeeding.
Do not use if you are vomiting, have nausea or if you have an ulcer, a dry cough due to Yin deficiency, or a case of excess dampness.

115. Known Adverse Reactions*
Not applicable.

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:

- **c) 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**
- **d) 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*
John Lee	*John Lee*	2 0 0 6 0 9 2 2

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.

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

APPENDIX 3: EXAMPLE OF A NON-TRADITIONAL APPLICATION

Health Canada / Santé Canada

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* Natural Inc.			5. Company Code (If known) 12345
6. Address: Street/Suite/PO Box* 123 Smart Rd			
7. City – Town* New York	9. Province – State* New York	8. Country* USA	10. Postal/ZIP Code* 12345-1234

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

11. Name ■ Mr. □ Ms. □ Dr. Surname* Smith Given Name* John		12. Title President	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.* (212) 555-1234	Ext. 101	22. Fax No. (212) 555-4321	23. E-mail john_smith@naturelle.com

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* Marleau Given Name* Marie		Regulatory Affairs Associate	
28. Company Name (*if different from Applicant/Licensee) Regulatory Affairs Consultant Inc.			**29. Address same as "A" □**
30. Street/Suite/PO Box* 123 Natural Rd.			
31. City – Town* Mississauga	33. Province – State* Ontario	32. Country* Canada	34. Postal/Zip Code* L4M 2H8

35. Telephone No.* (905) 555-2345	Ext. 201	36. Fax No. (905) 555-5432	37. E-mail mmarleau@rac-car.com

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* Johnson Given Name* Ann		President	
42. Company Name (* if different from Applicant/Licensee) Regulatory Consulting Company Inc.			**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.* (905) 555-2345	Ext. 101	50. Fax No. (905) 555-5432	51. E-mail ajohnson@rac-car.com

E. – CONTACT TO WHOM THE PRODUCT LICENCE IS TO BE SENT:	**52. As Above: B:□ C:■ D: □** Not Applicable:□ Name:_____ (check only one box)

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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: 1	■ Animal tissue form(s)	#: 2	1
■ Product licence application form	□ Designated Party Authorization form:		
□ Additional pages for Product Information	■ Label Text	#: 2	1
□ Additional pages for Site Information	□ TPD Label Text (Transitional DIN or Homeopathic DIN)	#:	
■ Evidence Summary Report:	■ Quality Summary Report:		1
■ Safety Summary Report:	■ Other, Claim Evidence: full-text articles		1

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 #: OF9-00-0-10000-1-1 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: _____

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 3 – SITE INFORMATION

62. Company Name Natural Inc.			63. ■ Manufacturer SL# not required ☐ Packager SL# _____ ☐ Labeller SL# _____ ☐ Importer SL# _____ ☐ Distributor
64. Number, Street – Suite – PO Box 123 Smart Rd			
65. City New York			
66. Province – State New York	67. Country USA	68. Postal Code – Zip Code 12345-1234	
62. Company Name Packager and Labeller Corp.			63. ☐ Manufacturer SL# _____ ■ Packager SL# 312345 ■ Labeller SL# 312345 ■ Importer SL# 312345 ☐ Distributor
64. Number, Street – Suite – PO Box 111 Boul. St. Laurent			
65. City Montréal			
66. Province – State Québec	67. Country Canada	68. Postal Code – Zip Code H2W 1X8	
62. Company Name Distributing Natural Inc.			63. ☐ Manufacturer SL# _____ ☐ Packager SL# _____ ☐ Labeller SL# _____ ☐ Importer SL# _____ ■ Distributor
64. Number, Street – Suite – PO Box 123 Distributing Rd.			
65. City Kingston			
66. Province – State Ontario	67. Country Canada	68. Postal Code – Zip Code K2H 1M8	
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: _____			

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

70. Primary Brand Name* ABC - OMEGA

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.		Fish oil	Aug 8/06	Fish oil	Fish oil	350 mg		X	X	
2.										
3.				*Borago officinalis*	Borage oil	350 mg		X		X
4.		Flax	May 15/06	*Linum usitatissimum*	Flaxseed oil	350 mg		X		X
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.	18%	EPA	sardine, anchovy, mackerel					cold pressed
2.	12%	DHA						
3.	20%	GLA	seed					
4.	150 mg	LA	seed					
5.	180 mg	ALA						
6.								
7.								
8.								
9.								
10.								
11.								
12.								

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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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.		Glycerin	Capsule coating agent		X
2.		Gelatin	Capsule coating agent	X	
3.		Vitamin E	Anti-oxidant		X
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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

D. – RECOMMENDED CONDITIONS OF USE

102. Recommended Use or Purpose*
Omega-3 supplement for the maintenance of good health.
Helps support cardiovascular health.

103. Dosage Form (one only)*	104. Sterile*	105. Route of Administration*
Capsule	□ Yes ■ No	Oral

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.)		
Adult	1 – 3	Capsules	Daily	With a meal.

Risk Information

113. Cautions and Warnings*
Do not use if pregnant or breastfeeding.

114. Contraindications*
Consult a health care practitioner prior to use if you are taking blood thinners or if you have a bleeding disorder.

115. Known Adverse Reactions*
Not applicable.

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:

e) 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

f) 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*
John Smith	*John Smith*	2 0 0 6 0 9 2 2

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.

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

APPENDIX 4: EXAMPLE OF A TPD CATEGORY IV/LABELLING STANDARD APPLICATION

Health Canada / Santé Canada

PRODUCT LICENCE APPLICATION FORM
Natural Health Products Directorate

Protected when completed

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

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* Herbs and Vitamins Inc.			5. Company Code (If known)
6. Address: Street/Suite/PO Box* 123 Union Street			
7. City – Town* Ottawa	9. Province – State* Ontario	8. Country* Canada	10. Postal/ZIP Code* K2H 1X3

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

11. Name ■ Mr. □ Ms. □ Dr. Surname* Lalonde Given Name* Guy		12. Title CEO	13. Language preferred: ■ English □ French
14. Company Name (* if different from Applicant/Licensee) Herbs Are Us Inc.			**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.* (613) 555-1234	Ext. 101	22. Fax No. (613) 555-4321	23. E-mail g_lalonde@herbsvitamins.com

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* Thompson Given Name* Gary		Regulatory Affairs Associate	
28. Company Name (*if different from Applicant/Licensee) Herbs and Vitamins Inc.			**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.* (613) 555-1234	Ext. 201	36. Fax No. (613) 555-4321	37. E-mail g_thompson@herbsvitamins.com

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)

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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: 1	□ Animal tissue form(s)	#: _____	_____
■ Product licence application form	□ Designated Party Authorization form:		_____
□ Additional pages for Product Information	■ Label Text	#: 2	1
□ Additional pages for Site Information	□ TPD Label Text (Transitional DIN or Homeopathic DIN)	#: _____	_____
□ Evidence Summary Report:	■ Quality Summary Report:		1
□ Safety Summary Report:	■ Other, Claim Evidence: Category IV Monograph – Sunburn Protectants		1

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: _____

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 3 – SITE INFORMATION

62. Company Name Herbs and Vitamins Inc.			63. ■ Manufacturer SL# 312346 ■ Packager SL# 312346 ■ Labeller SL# 312346 ☐ Importer SL# ___ ■ Distributor
64. Number, Street – Suite – PO Box 123 Union Street			
65. City Ottawa			
66. Province – State Ontario	67. Country Canada	68. Postal Code – Zip Code K2H 1X3	
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: ___			

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

VERSION 2.0

PART 4 – PRODUCT INFORMATION

70. Primary Brand Name* Very Pretty Foundation with SPF 15

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.		CATIV - Sunburn Protectants	Aug 28/02	Titanium Dioxide	Titanium Dioxide	15.0 %	X			X
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.			Synthetic					
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								

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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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.		Xanthan gum	Viscosity increasing agent		X
2.		Water	Solvent		X
3.		Vitamin E	Antioxidant		X
4.		Propylparaben	Preservative		X
5.		Propylene carbonate	Viscosity increasing agent		X
6.		Octyl stearate	Emollients		X
7.		PEG-10 dimethicone	Skin conditioning		X
8,		Iron oxides	Colouring agent		X
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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

D. – RECOMMENDED CONDITIONS OF USE

102. Recommended Use or Purpose*
Sunburn protectant SPF 25
UVA and UVB protection against sunburn

103. Dosage Form (one only)*	104. Sterile*	105. Route of Administration*
cream	□ Yes ■ No	Topical

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.)		
N/A	Apply liberally	Cream	As needed	Apply liberally before sun exposure.

Risk Information

113. Cautions and Warnings*
Avoid contact with eyes.

114. Contraindications*
Not applicable.

115. Known Adverse Reactions*
Not applicable.

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:

- **g) 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**
- **h) 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*
Guy Lalonde	*Guy Lalonde*	2 0 0 6 0 9 2 2

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.

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

APPENDIX 5: EXAMPLE OF TRANSITIONAL DIN PRODUCT LICENCE APPLICATION

Health Canada / Santé Canada

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* Sunshine Ideas Inc.			5. Company Code (If known) 12321
6. Address: Street/Suite/PO Box* 123 Main Street			
7. City – Town* Calgary	9. Province – State* Alberta	8. Country* Canada	10. Postal/ZIP Code* T2E 1X1

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

11. Name □ Mr. □ Ms. ■ Dr. Surname* Jones Given Name* Joanne		12. Title President	13. Language preferred: ■ English □ French
14. Company Name (* if different from Applicant/Licensee) Sunshine Ideas Inc.			**15. Address same as "A"** □
16. Street/Suite/PO Box* 123 Healthy Road			
17. City – Town* San Francisco	19. Province – State* California	18. Country* USA	20. Postal/Zip Code* 94114

21. Telephone No.* (415) 555-1234	Ext. 101	22. Fax No. (415) 555-4321	23. E-mail jjones@sunshineideas.com

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* Leduc Given Name* Louise		CEO	
42. Company Name (* if different from Applicant/Licensee) Sunshine Ideas Inc.			**43. Address same as "C"** □
44. Street/Suite/PO Box* 123 Main Street			
45. City – Town* Calgary	47. Province – State* Alberta	46. Country* **Canada**	48. Postal/Zip Code* T2E 1X1

49. Telephone No.* (403) 555-1234	Ext. 101	50. Fax No. (403) 555-4321	51. E-mail lleduc@sunshineideas.com

E. – CONTACT TO WHOM THE PRODUCT LICENCE IS TO BE SENT:	**52. As Above: B:□ C:□ D:■** Not Applicable:□ Name:_____ (check only one box)

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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#__12345678___)

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: ____1_____	□ Animal tissue form(s)	#: _____	_____
■ Product licence application form	□ Designated Party Authorization form:		_____
□ Additional pages for Product Information	■ Label Text	#: ____2_____	____1___
□ Additional pages for Site Information	■ TPD Label Text (Transitional DIN or Homeopathic DIN)	#: ____2_____	____1___
□ Evidence Summary Report:	■ Quality Summary Report:		____1___
□ 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: _____

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 3 – SITE INFORMATION

62. Company Name Sunshine Ideas Inc.			63. ■ Manufacturer SL# not required
64. Number, Street – Suite – PO Box 123 Healthy Road			■ Packager SL# not required
65. City San Francisco			■ Labeller SL# not required
66. Province – State California	67. Country USA	68. Postal Code – Zip Code 94114	☐ Importer SL# ___________
			☐ Distributor
62. Company Name Sunshine Ideas Inc.			63. ☐ Manufacturer SL# ___________
64. Number, Street – Suite – PO Box 123 Main Street			☐ Packager SL# ___________
65. City Calgary			☐ Labeller SL# ___________
66. Province – State Alberta	67. Country Canada	68. Postal Code – Zip Code T2E 1X1	■ Importer SL# 123456
			■ Distributor
62. Company Name			63. ☐ Manufacturer SL# ___________
64. Number, Street – Suite – PO Box			☐ Packager SL# ___________
65. City			☐ Labeller SL# ___________
66. Province – State	67. Country	68. Postal Code – Zip Code	☐ Importer SL# ___________
			☐ Distributor
62. Company Name			63. ☐ Manufacturer SL# ___________
64. Number, Street – Suite – PO Box			☐ Packager SL# ___________
65. City			☐ Labeller SL# ___________
66. Province – State	67. Country	68. Postal Code – Zip Code	☐ Importer SL# ___________
			☐ Distributor
62. Company Name			63. ☐ Manufacturer SL# ___________
64. Number, Street – Suite – PO Box			☐ Packager SL# ___________
65. City			☐ Labeller SL# ___________
66. Province – State	67. Country	68. Postal Code – Zip Code	☐ Importer SL# ___________
			☐ Distributor
69. Attach separate sheets (same format) if necessary. Number of pages attached: __________			

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

VERSION 2.0

Page 3 of 6

PART 4 – PRODUCT INFORMATION

70. Primary Brand Name* Sunshine Foundation with SPF 25

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.		CATIV - Sunburn Protectants	Aug 28/02	Titanium Dioxide	Titanium Dioxide	15.0 %	X			X
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.			Synthetic					
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								

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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

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.		Xanthan gum	Viscosity increasing agent		X
2.		Water	Solvent		X
3.		Vitamin E	Antioxidant		X
4.		Propylparaben	Preservative		X
5.		Propylene carbonate	Viscosity increasing agent		X
6.		Octyl stearate	Emollient		X
7.		PEG-10 dimethicone	Skin conditioning		X
8,		Iron oxides	Colouring agent		X
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

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

PART 4 – PRODUCT INFORMATION

D. – RECOMMENDED CONDITIONS OF USE

102. Recommended Use or Purpose*
Sunburn protectant SPF 25
UVA and UVB protection against sunburn

103. Dosage Form (one only)*	104. Sterile*	105. Route of Administration*
cream	□ Yes ■ No	Topical

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.)		
N/A	Apply liberally	Cream	As needed	Apply liberally before sun exposure.

Risk Information

113. Cautions and Warnings*
Avoid contact with eyes.

114. Contraindications*
Not applicable.

115. Known Adverse Reactions*
Not applicable.

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:

- **i) 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**
- **j) 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.**

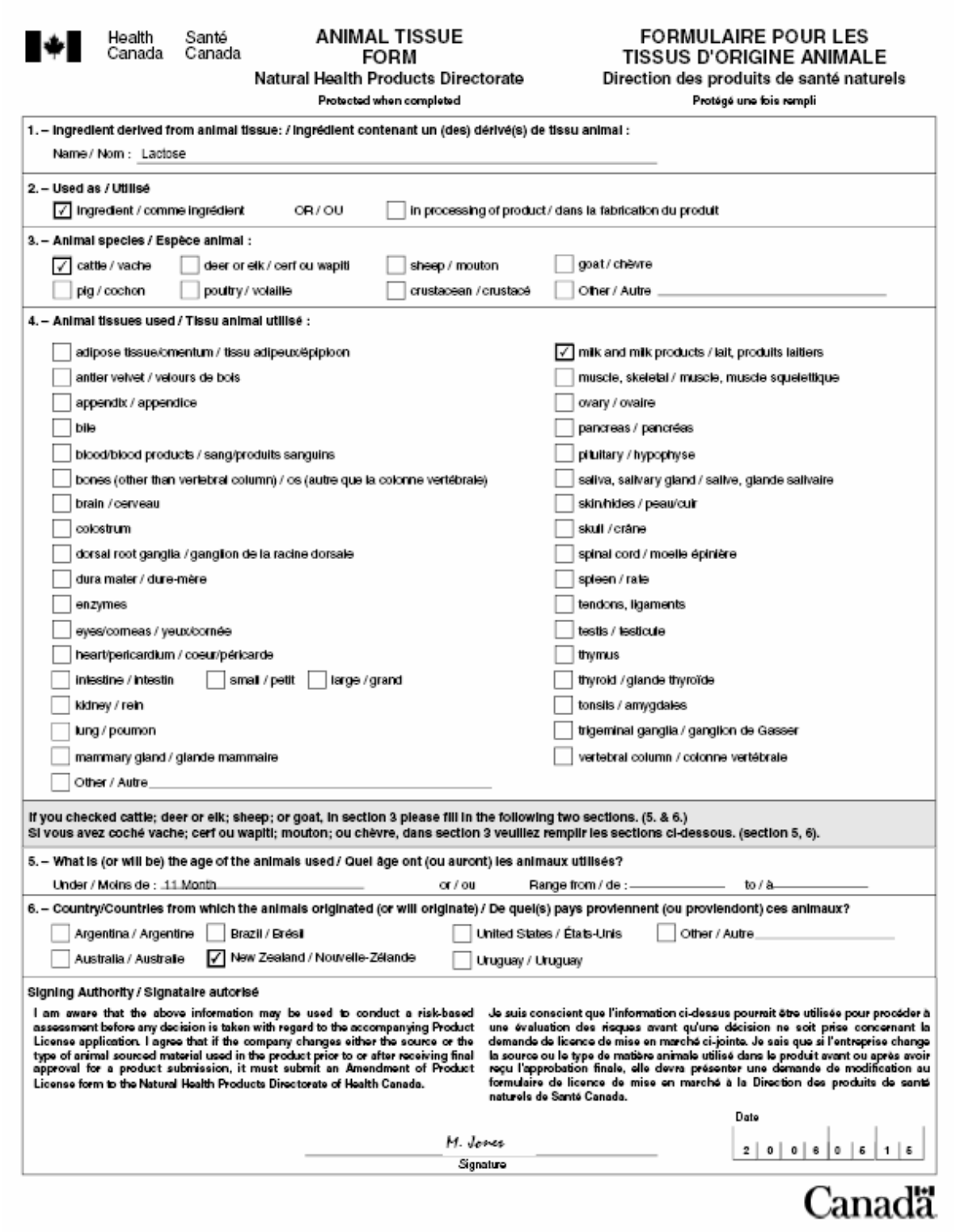
I, the undersigned, certify that the information and material included in this product licence application is accurate and complete".**

116. Name of Authorized Senior Official[1] (print)*	117. Signature*	118. Date*
Joanne Jones	*Joanne Jones*	2 0 0 6 0 9 2 2

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.

Copy this form as necessary
* - denotes mandatory
** - if yes, complete Animal Tissue Form

APPENDIX 6: EXAMPLE OF A COMPLETED ANIMAL TISSUE FORM



Health Canada / Santé Canada

ANIMAL TISSUE FORM
Natural Health Products Directorate
Protected when completed

FORMULAIRE POUR LES TISSUS D'ORIGINE ANIMALE
Direction des produits de santé naturels
Protégé une fois rempli

1. – Ingredient derived from animal tissue: / Ingrédient contenant un (des) dérivé(s) de tissu animal :

Name / Nom : Lactose

2. – Used as / Utilisé

☑ Ingredient / comme ingrédient OR / OU ☐ In processing of product / dans la fabrication du produit

3. – Animal species / Espèce animal :

☑ cattle / vache ☐ deer or elk / cerf ou wapiti ☐ sheep / mouton ☐ goat / chèvre
☐ pig / cochon ☐ poultry / volaille ☐ crustacean / crustacé ☐ Other / Autre

4. – Animal tissues used / Tissu animal utilisé :

☐ adipose tissue/omentum / tissu adipeux/épiploon
☐ antler velvet / velours de bois
☐ appendix / appendice
☐ bile
☐ blood/blood products / sang/produits sanguins
☐ bones (other than vertebral column) / os (autre que la colonne vertébrale)
☐ brain / cerveau
☐ colostrum
☐ dorsal root ganglia / ganglion de la racine dorsale
☐ dura mater / dure-mère
☐ enzymes
☐ eyes/corneas / yeux/cornée
☐ heart/pericardium / coeur/péricarde
☐ intestine / intestin ☐ small / petit ☐ large / grand
☐ kidney / rein
☐ lung / poumon
☐ mammary gland / glande mammaire
☐ Other / Autre

☑ milk and milk products / lait, produits laitiers
☐ muscle, skeletal / muscle, muscle squelettique
☐ ovary / ovaire
☐ pancreas / pancréas
☐ pituitary / hypophyse
☐ saliva, salivary gland / salive, glande salivaire
☐ skin/hides / peau/cuir
☐ skull / crâne
☐ spinal cord / moelle épinière
☐ spleen / rate
☐ tendons, ligaments
☐ testis / testicule
☐ thymus
☐ thyroid / glande thyroïde
☐ tonsils / amygdales
☐ trigeminal ganglia / ganglion de Gasser
☐ vertebral column / colonne vertébrale

If you checked cattle; deer or elk; sheep; or goat, in section 3 please fill in the following two sections. (5. & 6.)
Si vous avez coché vache; cerf ou wapiti; mouton; ou chèvre, dans section 3 veuillez remplir les sections ci-dessous. (section 5, 6).

5. – What is (or will be) the age of the animals used / Quel âge ont (ou auront) les animaux utilisés?

Under / Moins de : 11 Month or / ou Range from / de : _____ to / à _____

6. – Country/Countries from which the animals originated (or will originate) / De quel(s) pays proviennent (ou proviendont) ces animaux?

☐ Argentina / Argentine ☐ Brazil / Brésil ☐ United States / États-Unis ☐ Other / Autre
☐ Australia / Australie ☑ New Zealand / Nouvelle-Zélande ☐ Uruguay / Uruguay

Signing Authority / Signataire autorisé

I am aware that the above information may be used to conduct a risk-based assessment before any decision is taken with regard to the accompanying Product License application. I agree that if the company changes either the source or the type of animal sourced material used in the product prior to or after receiving final approval for a product submission, it must submit an Amendment of Product License form to the Natural Health Products Directorate of Health Canada.

Je suis conscient que l'information ci-dessus pourrait être utilisée pour procéder à une évaluation des risques avant qu'une décision ne soit prise concernant la demande de licence de mise en marché ci-jointe. Je sais que si l'entreprise change la source ou le type de matière animale utilisé dans le produit avant ou après avoir reçu l'approbation finale, elle devra présenter une demande de modification au formulaire de licence de mise en marché à la Direction des produits de santé naturels de Santé Canada.

M. Jones
Signature

Date: 2 0 0 8 0 5 1 5

Canada

APPENDIX 7: NON-MEDICINAL INGREDIENT LIST OF PURPOSES

Abrasives (for use in topically or dentally applied products ONLY): Used to remove unwanted tissue or foreign materials from various body surfaces. The removed materials may include dead skin surface cells, callus, or dental plaque. As a rule, abrasives are irregularly shaped fine or coarse solids. Harder abrasives include special forms of hydrated silica used for tooth cleansing, while softer abrasives such as oatmeal are employed to remove dead skin surface cells.

Acidifying agents (acidulants): Used in liquid preparations to provide acidic medium for product stability (e.g. lactic acid, hydrochloric acid).

Additives, colour (colouring agents): Used to impart colour to liquid and solid (e.g. tablets and capsules) formulations (e.g. D&C Orange #10 Lake, Flaming Red (D&C Red #36)).

Adhesives (for use in topically applied products ONLY): Substances that tend to bind opposite surfaces to each other. Adhesives are generally applied from a solvent solution (usually water) and allowed to dry on the two facing surfaces. A typical example is hydroxypropyl methyl cellulose.

Adsorbents: Ingredients, usually solids, with a large surface area which can attract dissolved or finely dispersed substances from another medium by physical or chemical (chemisorption) means (e.g. bentonite, cellulose).

Aerosol propellants: Substances responsible for developing the pressure within an aerosol container and expelling the product when the valve is open.

Air displacement agents: Substances employed to displace air in a hermetically sealed container to enhance product stability (e.g. nitrogen, carbon dioxide).

Alkalizing agents: Substances used in liquid preparations to provide alkaline medium for product stability (e.g. diethanolamine, potassium citrate).

Anticaking agents: Ingredients used to prevent the agglomeration of a particulate solid into lumps or cohesive cakes. (e.g. calcium phosphate tribasic, talc).

Anticoagulants: Substances used to prevent ingredients from changing from a fluid state to more or less solid state (e.g. edetic acid, (EDTA)).

Antifoaming agents: Chemicals which reduce the tendency of finished products to generate foam on shaking or agitation. The ability to control foaming is important during the mixing and filling of products and in those products which should not foam during consumer use. The absence of foam provides the consumer with air-free products and facilitates maintenance of consistent fill weights during bottling. Called antifoams for short.

Antifungal preservative: Substance used in liquid and semi-solid preparations to prevent the growth of fungi. The effectiveness of the parabens is usually enhanced when they are used in combination (e.g. butylparaben, ethylparaben).

Antimicrobial preservatives: Used in liquid and semi-solid preparations to prevent the growth of microorganisms (e.g. benzoic acid, benzyl alcohol).

Antioxidant synergists: Substances that improve the function of an antioxidant helping it to inhibit oxidation and thus is used to prevent the deterioration of preparations by the oxidative process (e.g. edetic acid (EDTA)).

Antioxidants: Ingredients employed to prevent or retard product spoilage from rancidity or by inhibiting oxidation (deterioration from reaction with oxygen). (e.g. ascorbic acid, propyl gallate).

Antistatic agents (for use in topically applied products ONLY): Ingredients that alter the electrical properties of materials or of human body surfaces (skin, hair, etc.) by reducing their tendency to acquire an electrical charge.

Bases: Agents used as a vehicle into which medicinal substances are incorporated (e.g. polydextrose, lanolin, hard fat).

Binders: Ingredients added to compounded dry powder mixtures of solids and the like to provide adhesive qualities during and after compression to make tablets or cakes. Many lipids, surfactants, and polymers can be used for the indicated purpose (e.g. acacia, gelatin).

Buffering agents: Chemicals which have the property of maintaining the pH of an aqueous medium in a narrow range even if small amounts of acids or bases are added. Buffering agents and pH adjusters are used to alter and to maintain a product's pH at the desired level (e.g. malic acid, sodium citrate). Called buffers for short.

Bulking agents: Usually chemically inert, solid ingredients employed as diluents for other solids. In this application bulking agents are, for example, useful in the extension of pigments for use in a powder.

Capsule/tablet coating agent: Substance used to coat a formed tablet for the purpose of protecting against drug decomposition by atmospheric oxygen or humidity, to provide the desired release pattern for the substance after administration, to mask the taste or odour of the drug substance, or for aesthetic purposes (e.g. liquid glucose, ethylcellulose).

Capsule/tablet diluents (diluents): Inert substances used as fillers to create the desired bulk, flow properties, and compression characteristics in the preparation of tablets and capsules (e.g. calcium sulfate, sorbitol).

Capsule/tablet direct compression excipient: Substance used in direct compression tablet formulations (e.g. dibasic calcium phosphate).

Capsule/tablet disintegrants (disintegrants): Substances used in solid dosage forms to promote the disruption of the solid mass into smaller particles which are more readily dispersed or dissolved (e.g. alginic acid, carboxymethylcellulose).

Capsule/tablet glidant: Substance used in tablet and capsule formulations to improve the flow properties of the powder mixture (e.g. colloidal silica).

Capsule/tablet lubricants (lubricants): Substances used in tablet formulations to improve the flow properties of the powder mixture (e.g. calcium stearate, canola oil).

Capsule/tablet opaquant: Substance used to render a capsule or a tablet coating opaque. May be used alone or in combination with a colorant (e.g. titanium dioxide).

Chelating agents: Ingredients that have the ability to complex with and inactivate metallic ions in order to prevent their adverse effects on the stability or appearance of products. At times it is important to complex calcium or magnesium ions which are incompatible with a variety of ingredients. Chelation of ions, such as iron or copper, helps retard oxidative deterioration of finished products (e.g. edetic acid (EDTA), maltol). Also called sequestrants.

Clarifying agent: Substance used as a filtering aid because of its adsorbent qualities (e.g. bentonite).

Coating agents: Substances used to coat a solid formulation in order to aid in stability or improve the taste or odour (e.g. sugar adjunct, cetyl alcohol).

Colouring agents (Colorant): Substances used to impart colour to liquid and solid (e.g. tablets and capsules) formulations (e.g. D&C Orange #10 Lake, Flaming Red (D&C Red #36)).

Controlled release vehicles (Extended release agents): Ingredients in a delivery system that allows the medicinal component in a formulation to be released over time (e.g. microcrystalline wax, yellow wax).

Cosmetic (for use in topically or dentally applied products ONLY): The use of small amounts of substances such as NHPs in a product that is manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth in such amounts as to not exert a medicinal effect.

Cosmetic astringents (for use in topically applied products ONLY): Ingredients intended to induce a tightening or tingling sensation on skin.

Delivery systems: Substances used to improve the delivery of the medicinal ingredient through its route of administration (e.g. aliphatic polyesters).

Denaturants (for use in topically applied products ONLY): Ingredients added to ethyl alcohol to make it unsuitable for product intended to be administered orally. The materials used usually have an intensely bitter taste that renders the alcohol unpalatable.

Dessicants: Substances that trap moisture (e.g. calcium sulfate, anhydrous).

Detergents: Substances used to change the surface tension of a formulation to form an emulsion around certain ingredients (e.g. sodium lauryl sulfate).

Diluents: Substances used to dilute or reduce the concentration of the medicinal ingredient (e.g. calcium sulfate, sorbitol).

Disinfectants (Antimicrobial preservatives, Antiseptics) (for use in topically or ophthalmically applied products ONLY): Substances used in liquid and semi-solid preparations to prevent the growth of microorganisms (e.g. phenolic acid, benzalkonium chloride).

Disintegrants: Substances used in solid dosage forms to promote the disruption of the solid mass into smaller particles which are more readily dispersed or dissolved (e.g. alginic acid, carboxymethylcellulose).

Dispersing agents (Suspending agents): Substances that help maintain the dispersion of small particles in a formulation (e.g. poloxamer, sorbitan esters).

Dissolution enhancing agents: Substances that alter the molecular forces between ingredients to enhance the dissolution of the solute in the solvent (e.g. fructose, povidone).

Dusting powders: Powdery substances used to improve the sensory characteristics of a formulation (e.g. cornstarch, modified starch).

Dyes (colouring agents): Substances used to impart colour to formulations (e.g. Helindone Pink (D&C Red #30), Indigotine (FD&C Blue #2)).

Emollients (for use in topically applied products ONLY): Substances used to soften and soothe the skin (e.g. cetearyl alcohol, cholesterol).

Emulsifying agents: Substances used to promote and maintain the dispersion of finely subdivided particles of a liquid in a vehicle in which it is immiscible. The efficacy of emulsifying agents depends on their ability to reduce surface tension, to form complex films on the surface of emulsified droplets, and to create a repulsive barrier on emulsified droplets to prevent their coalescence. The end product may be a liquid emulsion or semisolid emulsion (e.g. a cream) (e.g. acacia, oleic acid).

Emulsion stabilizers: Ingredients that assist in the formation and the stabilization of emulsions. Emulsifying agents are required for the formation of emulsions, but their activity is materially enhanced whenever an emulsion stabilizer is included in the system. Emulsion stabilizers do not

act as primary emulsifiers but prevent or reduce the coalescence of emulsified droplets by modifying the continuous or the disperse phase of the emulsion. This stabilization may result from electrical repulsion, from changes in viscosity, or from film formation on the droplet surface (e.g. lecithin).

Emulsion stabilizer (Stabilizing agents): Substances that maintain the dispersion of subdivided particles in a liquid vehicle in which it is immiscible (e.g. white wax, yellow wax).

Encapsulating agent: Substance used to form thin shells for the purpose of enclosing a substance or formulation for ease of administration (e.g. gelatin, cellulose acetate phthalate).

Extended release agents (Controlled release agents): Ingredients in a delivery system that allow the medicinal component in a formulation to be released over time. (e.g. carrageenan, cellulose acetate).

Fillers: Substances that allow tabletting of small amounts of medicinal ingredients to be large enough to manufacture (e.g. ethylcellulose, lactose).

Film formers: Materials which, upon drying, produce a continuous film. These films are used for diverse purposes (e.g. gelatin, polymethacrylates).

Flavour enhancers (Flavouring agents): Used to impart a pleasant flavour and often odour to a pharmaceutical preparation. In addition to natural flavourings, many synthetic flavourings are also used (e.g. ethyl maltol).

Flavouring agents (Flavour enhancers): Substances used to impart a pleasant flavour and often odour to a pharmaceutical preparation. In addition to natural flavourings, many synthetic flavourings are also used (e.g. ethyl maltol, ethyl vanillin).

Flavouring fixative tablet binders (Tablet binders): Substances used to cause adhesion of flavour ingredients in tablet granulations (e.g. acacia, gelatin).

Flow enhancers: Substances used to improve the flow properties of a formulation (e.g. colloidal silicon dioxide).

Fragrance ingredients: According to the International Fragrance Association, fragrance ingredients are “any basic substance used in the manufacture of fragrance materials for its odorous, odour-enhancing or blending properties”. Fragrance ingredients may be obtained by chemical synthesis from synthetic, fossil, or natural raw materials, or by physical operations from natural sources. The function comprises aroma chemicals, essential oils, natural extracts, distillates and isolates, oleoresins, etc.

Gelling agents: Substances that have the capability to form a gel. Sometimes used as stabilizers (e.g. carrageenan, gelatin).

Glidants: Substances used to improve the flow properties of a formulation (e.g. magnesium trisilicate, powdered cellulose).

Granulating agents: Substances used to give granular shape to a formulation (e.g. maltitol, polydextrose).

Humectants (for use in topically applied products ONLY): Ingredients used to retard moisture loss from the product during use (e.g. glycerin, propylene glycol). This function is generally performed by hygroscopic materials. The efficacy of humectants depends to a large extent on the ambient relative humidity.

Hydrophilic matrix formation: Process using substances to form a matrix for a hydrophilic formulation (e.g. polyethylene oxide).

Levigating agent: Liquid used as an intervening agent to reduce the particle size of a powder by grinding together, usually in a mortar (e.g. mineral oil).

Lubricants: Substances that allows tablets to be ejected from its mold without fracture (e.g. calcium stearate, canola oil).

Mucoadhesives: Substances that bind to mucin (i.e. any of the mucoproteins that occur especially in secretions of mucous membranes) (e.g. polyethylene oxide).

Nonionic surfactants (Surfactants): Substances that absorb to surfaces or interfaces to reduce surface or interfacial tension (e.g. docusate sodium, cetrimide).

Ointment bases (for use in topically applied products ONLY): Semisolid vehicle into which drug substances may be incorporated in preparing medicated ointments (e.g. lanolin alcohol, petrolatum).

Oleaginous vehicles: A carrying agent for a medicinal ingredient with oily properties (e.g. canola oil, cottonseed oil).

Opacifying agents: Ingredients deliberately added to products to reduce their clear or transparent appearance. Some opacifying agents provide the pearly appearance desired in certain products. Other opacifying agents are used for covering purposes and to hide blemishes. Most emulsions and suspensions are opaque as a result of the presence of a liquid or solid disperse phase. Thus, a very large number of substances could be classified as opacifying agents.

Oxidizing agents: Chemicals which gain electrons during their reaction with a reducing agent. Oxidizing agents commonly contribute oxygen to other substances. Oxidizing agents are mainly used to destroy the natural pigment, melanin (i.e., effect bleaching), and restore the normal oxidized state of skin after exposure to a reducing agent.

Penetrants, skin (Skin penetrants) (for use in topically applied products ONLY): Substances that promote the passage of the medicinal ingredient into the skin (e.g. alcohol, oleic acid)

Penetration enhancing agents (for use in topically applied products ONLY): Substances that promote the passage of the medicinal ingredient through its route of administration (e.g. isopropyl myristate).

pH adjusters: Chemicals (acids, bases, or buffering agents) which are used to control the pH of finished products.

Pigments (Colouring agents): Substances used to impart colour to liquid and solid formulations (e.g. titanium dioxide).

Plasticizers: Materials which soften synthetic polymers. They are frequently required to avoid brittleness and cracking of *film formers*. Water, sometimes in combination with hygroscopic materials, is the common plasticizer for natural polymers and proteins. A variety of organic substances, such as esters, have been found useful for plasticizing synthetic polymers (e.g. lanolin alcohols, mineral oil).

Polishing agents: Substances used to impart an attractive sheen (e.g. yellow wax).

Preservatives, antimicrobial (Antimicrobial preservatives): Ingredients which prevent or retard microbial growth and thus protect products from spoilage (e.g. benzoic acid, benzyl alcohol). The use of preservatives is required to prevent product damage caused by microorganisms and to protect the product from inadvertent contamination by the consumer during use. The use of more than one preservative can sometimes increase efficacy due to synergism. Ingredients used to protect products against oxidative damage are classified as *antioxidants*.

Propellants: Chemicals used for expelling products from pressurized containers (aerosols). The functionality of a propellant depends on its vapor pressure at ambient temperature and its compressibility. Liquids or gases can be used as propellants as long as the pressure developed within the container is safely below the container's bursting pressure under normal storage and use conditions.

Protectants: Substances that provide a physical protection from the effects of the active ingredient (e.g. petrolatum).

Reducing agents: Chemicals which, during their reaction with oxidizing agents, lose electrons. Reducing agents commonly contribute hydrogen to other substances. They can be used as Antioxidants since they scavenge oxygen.

Sequestering agents: Substances whose molecular structure can envelop and hold a certain type of ion and alters its interaction with other ingredients (e.g. potassium citrate, tartaric acid).

Skin-conditioning agents – emollient (for use in topically applied products ONLY): Ingredients which help to maintain the soft, smooth, and pliable appearance of skin. Emollients function by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking, and to improve the skin's appearance. Similar functions are served by *Skin conditioning agents - humectant; Skin conditioning agents - miscellaneous; and especially Skin conditioning agents - occlusive*.

Skin-conditioning agents – humectant (for use in topically applied products ONLY): Ingredients intended to increase the water content of the top layers of skin. This group of ingredients includes primarily hygroscopic agents employed for this specific purpose. A similar function is attributed to *Skin-conditioning agents - emollient; Skin-conditioning agents - miscellaneous; and Skin-conditioning agents - occlusive.*

Skin-conditioning agents – miscellaneous (for use in topically applied products ONLY): Ingredients used to create special effects on skin. This group includes substances believed to enhance the appearance of dry or damaged skin and substantive materials which adhere to the skin to reduce flaking and restore suppleness. A similar effect is attributed to *Skin-conditioning agents - emollient; Skin-conditioning agents - humectant; and Skin-conditioning agents - occlusive*.

Skin-conditioning agents – occlusive (for use in topically applied products ONLY): Ingredients which retard the evaporation of water from the skin surface. This function is different from that of Antiperspirant agents which interfere with the delivery of liquid water to the skin surface. By blocking the evaporative loss of water, occlusive materials increase the water content of skin. Occlusive agents are generally lipids which tend to remain on the skin surface. Occlusivity is frequently attributed to *Skin-conditioning agents -– emollient, Skin-conditioning agents - humectant and Skin-conditioning agents - miscellaneous* which sometimes exhibit occlusive properties upon application to the skin.

Skin penetrants (for use in topically applied products ONLY): Substances that promote the passage of the medicinal ingredient into the skin (e.g. alcohol, oleic acid).

Slip modifiers: Ingredients used to enhance the flow properties of other ingredients. Slip modifiers do not react chemically with the material(s) to which they are added.

Solubilizing agents: Substances that alter the molecular forces between ingredients to allow the solute to dissolve in the solvent (e.g. benzalkonium chloride, polyethoxylated castor oil).

Solvents: Substances used to dissolve another substance in a solution. The solvent may be aqueous or non-aqueous (e.g. oleaginous). Cosolvents such as water and alcohol (hydroalcoholic) and water and glycerin may be used when needed (e.g. alcohol, glycerol).

Stabilizing agents: Substances that maintain physical aggregation, conformational and colloidal stability and experimental or prevent chemical degradation due to oxidation and photolytic reactions (e.g. albumin, glyceryl monostearate).

Stiffening agents: Substances used to increase the thickness or hardness of a pharmaceutical preparation, usually an ointment (e.g. cetyl alcohol, paraffin).

Suppository bases: Substances used as a vehicle into which medicinal substances are incorporated in the preparation of suppositories (e.g. hard fat, polyethylene glycol).

Surface modifiers: Substances that may be added to other ingredients to make them more hydrophilic or hydrophobic. As a rule, surface modifiers form a covalent bond with the substrate.

Surfactants: Substances that absorb to surfaces or interfaces to reduce surface or interfacial tension. May be used as cleansing agents, hydrotropes, or emulsifying agents (e.g. docusate sodium, cetrimide).

Surfactants – cleansing agents (for use in topically applied products ONLY): Surfactants used for skin and cleaning purposes and as emulsifiers. In this function, surfactants wet body surfaces, emulsify or solubilize oils, and suspend soil.

Surfactants – foam boosters (for use in topically applied products ONLY): Surfactants used to increase the foaming capacity of Surfactants - Cleansing agents, or to stabilize foams in general. Foam boosters are substances which increase the surface viscosity of the liquid which surrounds the individual bubbles in a foam.

Surfactants – hydrotropes: Surfactants which have the ability to enhance the water solubility of another surfactant. Prominent members of this group are short chain alkyl aryl sulfonates, sulfosuccinates, and some nonionic surfactants.

Surfactants - solubilizing agents: Surfactants which aid in the dissolution of an ingredient (solute) in a medium in which it is not otherwise soluble. This definition is specific and excludes cosolvency, i.e., the use of a mixed solvent such as alcohols and water in a clear fragrance product. It also excludes changes in solubility affected by pH modification, such as the dissolution of lauric acid in aqueous ammonium hydroxide.

Surfactants – suspending agents: Substances used to help distribute an insoluble solid in a liquid phase. Suspensions or dispersions of liquids in a second liquid are generally called emulsions.

Suspending agents (Dispersing agents) – nonsurfactant: A group of ingredients which facilitate the dispersion of solids in liquids. They function primarily by coating the solid through the process of adsorption, thus changing the surface characteristic of the suspended solid. The resultant suspensions may be formulated for use orally, ophthalmically, topically or by other routes (e.g. alginic acid, bentonite).

Sustained release ingredients (Extended-release ingredients): Ingredients in a delivery system that allow the medicinal component in a formulation to be released over time. (e.g. carrageenan, cellulose acetate).

Sweetening agents: Substances used to impart sweetness to a formulation (e.g. acesulfame potassium, glycerol).

Tablet anti-adherent: Substances that prevent the sticking of tablet formulation ingredients to punches and dyes in a tableting machine during production.

Tablet binders (Binders): Substances used to cause adhesion of powder particles in tablet granulations (e.g. acacia, gelatin).

Thickening agents: Substances used to change the consistency of a preparation to render it more resistant to flow (e.g. hydroxypropyl cellulose, polyethylene oxide).

Tonicity agents: Substances used to render a solution similar in osmotic dextrose characteristics to physiologic fluids (e.g. dextrose, potassium chloride).

Viscosity-decreasing agents: Substance used to enhance the fluidity of products without a significant lowering of the concentration of the active constituents. Inorganic salts, organic salts, Solvents, and a few selected substances have the ability to lower the viscosity of products. Their efficacy depends on their concentration and is highly specific for each type of product.

Viscosity-increasing agents: Substances used to change the consistency of a preparation to render it more resistant to flow. Used in suspensions to deter sedimentation, in ophthalmic solutions to enhance contact time or to thicken topical creams (e.g. cetearyl alcohol, sodium alginate).

Viscosity-increasing agents – aqueous: Substances used to thicken the aqueous portions of products. Their ability to perform this function is related to their water solubility or hydrophilic nature.

Viscosity-increasing agents – nonaqueous: Substances used to thicken the lipid portions of products. Their performance is the result of their water insolubility and compatibility with various lipids. They are widely used to thicken or gel various types of oleaginous products.

Vitamins, Stabilizing agents for: A substance that helps to prevent deterioration of a vitamin, thus maintaining stability (e.g. propylene glycol).

Water-absorbing agents: Substances that can hold water, thereby altering the thickness of a formulation (e.g. carboxymethylcellulose calcium).

Water-miscible cosolvents: A solvent that is able to mix with water (e.g. edetic acid (EDTA)).

Wetting agents: A substance, usually a surface-active agent, which reduces the surface tension of a liquid and therefore increases its adhesion to a solid surface (e.g. benzalkonium chloride, poloxamer).

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APPENDIX 8: LIST OF ACCEPTABLE DOSAGE FORMS

Dosage form. The final physical form of the NHP that may be used by the consumer without requiring any further manufacturing.

Note: Applicants are not limited to using dosage forms on this list.

Dosage Form	Definition	Synonyms	Route of Administration
Aerosol	A pressurized pharmaceutical form that contains medicinal agents released upon activation of an appropriate valve system.	Aerosol (without propellant)	Inhalation, topical, nasal
Aerosol, metered dose	A pressurized pharmaceutical form that contains medicinal agents and consists of a metered dose valve that allows for the delivery of a uniform quantity of spray upon each activation.		Inhalation, topical, nasal
Bar, chewable	A solid pharmaceutical form that contains medicinal agents usually in the form of a rectangle from which a segment can be detached as a dosage unit. It is meant to be chewed.		Oral
Bulk/loose	Any plant material to be used as a final dosage form.		Oral, buccal, topical, rectal, sublingual, transdermal, vaginal, otic, nasal, ophthalmic
Capsule	A solid pharmaceutical form that contains medicinal agents within either a hard or soft soluble container or shell. The shells are made of gelatin or other substance.		Oral
Capsule, combined release	A capsule that consists of two or more medicinal agents with different delivery characteristics (e.g. immediate release and extended release).	Capsule, dual release, repeat action	Oral
Capsule, delayed release	A capsule formulated to release the medicinal agents at any time other than promptly after administration.	Enteric coated, repeat action	Oral
Capsule, extended release	A capsule formulated to release the medicinal agents in such a manner to allow a reduction in dosing frequency as compared to that of the medicinal agents presented as a conventional dosage form.	Sustained release, prolonged release, controlled release, timed release	Oral
Collodion-like solution	A solution containing pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent that leaves a transparent cohesive film when applied to the skin in a thin layer.		Topical

Dosage Form	Definition	Synonyms	Route of Administration
Compress	A cloth or another material applied under pressure to an area of the skin and held in place for a period of time. A compress can be any temperature (cold, lukewarm, or hot) and it can be dry or wet. It may also be impregnated with medication or, in traditional medicine, an herbal remedy. Most compresses are used to relieve inflammation.		Topical
Cream	A semi-solid pharmaceutical form that contains medicinal agents dissolved or dispersed in either an oil-in-water emulsion or in another type of water-washable base.		Topical, transdermal
Cream, liposomal	A semi-solid pharmaceutical form that contains medicinal agents and consists of solid particles dispersed in either an oil-in-water emulsion or in another type of water-washable base.		Topical, transdermal
Dentifrice, gel	A gel formulation that contains medicinal agents intended to clean and polish the teeth.	Toothpaste	Dental
Dentifrice, paste	A paste formulation that contains medicinal agents intended to clean and polish the teeth.	Toothpaste	Dental
Douche	A liquid pharmaceutical form containing medicinal agents dissolved in a suitable solvent or mutually miscible solvents that is prepared from powders, liquid solutions or liquid concentrates. It is intended for the irrigative cleansing of the vagina.		Vaginal
Dressing	An external application that contains medicinal agents, resembles an ointment, and is usually used as a covering or protection.		Topical, rectal, vaginal, ophthalmic, otic
Elixir	A clear, pleasantly flavoured and sweetened hydro-alcoholic liquid that contains dissolved medicinal agents. It is intended for oral use.		Oral
Emulsion	A two-phase system that contains medicinal agents, in which one liquid is dispersed through another liquid in the form of small droplets.		Topical
Enema	A solution introduced into the rectum to promote evacuation of feces or as a means of administering medicinal substances.		Rectal
Floss	A thread (waxed or unwaxed) that contains medicinal agents and is used for cleaning between the teeth.		Dental

Dosage Form	Definition	Synonyms	Route of Administration
Fluid extract	An alcoholic or hydro-alcoholic preparation providing a dry or fresh herb strength ratio of 1:1.		Oral, ophthalmic, topical, buccal, rectal, vaginal
Gel	A semi-solid pharmaceutical form that contains medicinal agents and consists of liquids gelled by means of suitable gelling agents.	Jelly	Topical, oral, vaginal, rectal
Gel, extended release	A gel formulated to release the medicinal agents in such a manner to allow a reduction in dosing frequency as compared to that of the medicinal agents presented as a conventional dosage form.	Sustained release, prolonged release, controlled release, timed release	Topical, oral, vaginal, rectal
Globules	A small globular mass made of pure sucrose, lactose or other appropriate polysaccharides that are medicated through a drug attenuation process.	Pellets, pillules	Oral For homeopathic products only
Glycerine extract	A type of extract prepared by treating a plant or a plant material, an alga, a bacterium, a fungus or an animal material with glycerine to obtain the desired compounds.		Oral, topical
Glycerine suspension	A suspension of medicinal ingredients in a glycerine medium		Oral, topical
Granule	A small particle or grain that contains medicinal agents. They are intended for oral administration. Some are swallowed as such, some are chewed and some are dissolved or dispersed in water or another liquid before being administered.		Oral
Granule, effervescent	A granule in a dry mixture usually composed of sodium bicarbonate, citric acid and tartaric acid that, when in contact with water, has the capability to release gas, resulting in effervescence.		Oral
Granule, delayed release	A granule formulated to release the medicinal agents at any time other than promptly after administration. Enteric coated.	Enteric coated	Oral
Gum, chewing	A solid, single-dose preparation that contains medicinal agents, with a base consisting mainly of gum. It is intended to be chewed but not swallowed.		Oral

Dosage Form	Definition	Synonyms	Route of Administration
Liquid	The state of matter in which a substance exhibits a characteristic readiness to flow, little or no tendency to disperse, relatively high incompressibility and, whose shape is usually determined by the container it fills. Furthermore, liquids exert pressure on the sides of a container as well as on anything within the liquid itself; this pressure is transmitted undiminished in all directions.		Oral, topical, sublingual, rectal, vaginal, transdermal, nasal, otic, ophthalmic, irrigation
Loose herb, herbal tea	One or more dried plant(s) contained in a sealed package (for example in a bag or box) used to prepare a beverage with therapeutic properties	Tisane, loose herb	Oral
Lotion	A broad term to describe a liquid or semi-liquid preparation that contains medicinal agents, with solid materials suspended in an aqueous vehicle. Lotions are usually a suspension of solids in an aqueous medium, but may also be emulsions or solutions.		Topical, transdermal, vaginal, rectal, otic, ophthalmic
Lozenge	A disc-shaped, solid pharmaceutical form that contains medicinal agents and sometimes flavouring in a hard candy or sugar base. It is intended to be slowly dissolved in the oral cavity, usually for localized effects, although some may be formulated for systemic absorption.	Pastilles, troche	Oral, sublingual
Mousse	A foamy preparation applied externally in a pressurized container		Topical
Mouthwash/ gargle	An aqueous solution that contains medicinal agents that are swished in the mouth or held in the throat and gargled and subsequently expectorated.		Buccal
Oil	Any one of a great variety of unctuous combustible substances, not miscible with water, which are generally slippery, combustible, viscous, liquid or liquefiable at room temperatures. They are of animal, plant, or mineral origin and of varied composition.		Oral, topical, otic, transdermal
Ointment	A semi-solid pharmaceutical form that contains medicinal agents consisting of a single-phase base in which solids or liquids may be dispersed.		Topical, vaginal, rectal, nasal, transdermal
Pad	A cushion-like mass of soft material that contains medicinal agents.	Pledglet	Topical, transdermal

Dosage Form	Definition	Synonyms	Route of Administration
Paste	A semi-solid pharmaceutical form of thick or stiff consistency that contains medicinal agents and large proportions of solids finely dispersed in the base. **Not to be used for toothpaste.**		Topical, transdermal
Patch	A drug delivery system that contains an adhesive backing and that permits the medicinal agents to diffuse from some portion of it (e.g. the backing itself, a reservoir, the adhesive, or some other component) into the body from the site where it is applied.		Transdermal, topical
Patch, extended release	A patch formulated to release the medicinal agents in such a manner to allow a reduction in dosing frequency as compared to that of the medicinal agents presented as a conventional dosage form.	Sustained release, prolonged release, controlled release, timed release	Transdermal, topical
Pellet	A small, sterile and solid mass consisting of a highly purified medicinal agent (with or without excipients) made by the formation of granules, or by compression and moulding.		For homeopathic products, use globule
Pencil	A solid paste containing medicinal agents, compacted into a tapered cylinder form imitating a common pencil in shape. It is intended for topical application on the skin or skin adnexa.		Topical
Piece, chewable	A solid or semi-solid pharmaceutical form of various shapes (e.g. cube, bear) that contains medicinal agents and is intended to be chewed and swallowed. It is smaller than a chewable bar, does not qualify as a chewable tablet and is not a gum.	Soft chew, gummy bear, candy	Oral
Plaster	A solid or semi-solid adhesive mass that contains medicinal agents and is spread on a backing material of paper, fabric, moleskin or plastic. Plasters are intended to afford protection and to support and furnish an occlusion and macerating action, and to bring medication into close contact with the skin.		Topical
Powder	An intimate mixture of dry, finely divided medicinal agents intended for internal or external use.		Oral, topical, inhalation, transdermal
Powder, effervescent	An intimate mixture of dry, finely divided medicinal agents in a dry mixture, usually composed of sodium bicarbonate, citric acid and tartaric acid, that when put in contact with water has the capability to release gas, resulting in effervescence.		Oral

Dosage Form	Definition	Synonyms	Route of Administration
Powder, delayed release	An intimate mixture of dry, finely divided medicinal agents formulated to release the medicinal agents at any time other than promptly after administration.		Oral, topical, transdermal
Powder for gel	An intimate mixture of dry, finely divided medicinal agents that upon the addition of suitable vehicles yields a gel.		Topical, oral
Powder for solution	An intimate mixture of dry, finely divided medicinal agents that upon the addition of suitable vehicles yields a solution.	Drops	Oral, topical, sublingual, rectal, vaginal, transdermal, nasal, otic, ophthalmic, irrigation
Powder for suspension, extended release	An intimate mixture of dry, finely divided medicinal agents that upon the addition of a suitable vehicle yields a suspension (a liquid preparation containing solid particles dispersed in the liquid vehicle). It is formulated to release the medicinal agents in such a manner to allow a reduction in dosing frequency as compared to that of the medicinal agents presented as a conventional dosage form.	Sustained release, prolonged release, controlled release, timed release	Oral, topical
Powder for suspension	An intimate mixture of dry, finely divided medicinal agents that upon the addition of a suitable vehicle yields a suspension (a liquid preparation containing solid particles dispersed in the liquid vehicle).		Oral, topical, sublingual, rectal, vaginal, transdermal, nasal, otic, ophthalmic
Powder, metered dose	A powder containing medicinal agents that is situated inside a container that has a mechanism to deliver a specified quantity.		Oral, inhalation
Roll-on	A dosage form that allows the product to be applied by means of a rotating ball in the neck of the container		Topical
Shampoo	A liquid soap or detergent that contains medicinal agents and is used to clean the hair and scalp.		Topical
Soap, bar	A solid dosage form in the shape of a bar that contains medicinal agents and is used to cleanse the skin.		Topical
Soap, liquid	A liquid dosage form that contains medicinal agents and is used to cleanse the skin.		Topical

Dosage Form	Definition	Synonyms	Route of Administration
Softgel	A solid pharmaceutical form that contains medicinal agents within a soft soluble container or shell. The shells are made of gelatin or other substance.	Capsule, Softgel capsule	Oral
Solid Extract	A type of extract prepared by treating a plant or a plant material, an alga, a bacterium, a fungus or an animal material with solvents or by pressing to obtain the desired compounds, from which the solvent or expressed water has been removed by drying.		Oral
Solution	A liquid preparation that contains one or more chemical substances dissolved (i.e. molecularly dispersed) in a suitable solvent or mixture of mutually miscible solvents.	Drops	Oral, topical, ophthalmic, nasal, rectal, vaginal, transdermal
Solution, extended release	A liquid preparation containing one or more chemical substances dissolved (i.e. molecularly dispersed) in a suitable solvent or mixture of mutually miscible solvents that is formulated to release the medicinal agents in such a manner to allow a reduction in dosing frequency as compared to that of the medicinal agents presented as a conventional dosage form.	Sustained release, prolonged release, controlled release, timed release	Oral, topical
Sponge	An absorbent pad of folded gauze or cotton that contains medicinal agents.		Topical, vaginal
Spray	An aqueous or oleaginous solution, suspension or emulsion that contains medicinal agents in the form of coarse droplets or as finely divided solids to be applied topically, most usually to the nasal-pharyngeal tract or skin.	Aerosol (without propellant)	Inhalation, nasal, topical
Spray, metered dose	An aqueous or oleaginous solution that contains medicinal agents in the form of coarse droplets or as finely divided solids, and consists of a metered dose valve that allows for the delivery of a uniform quantity of spray upon each spray.		Inhalation, nasal, topical
Stick	A solid pharmaceutical form that contains medicinal agents dissolved or dispersed in a simple or compound excipient that may dissolve or melt at body temperature. It is intended for local application.		Topical
Strip	A long, narrow piece of medicated substance		Topical, oral
Succus	The expressed juice of a plant, for medicinal use.	Juice	Oral

Dosage Form	Definition	Synonyms	Route of Administration
Suppository	A solid body of varying weight and shape adapted for introduction into the rectal, vaginal or urethral orifice of the human body. It usually melts, softens or dissolves at body temperature.	Ovule	Rectal, vaginal
Suppository, extended release	A solid body of varying weight and shape adapted for introduction into the rectal, vaginal or urethral orifice of the human body that is formulated to release the medicinal agents in such a manner to allow a reduction in dosing frequency as compared to that of the medicinal agents presented as a conventional dosage form.	Sustained release, prolonged release, controlled release, timed release	Rectal, vaginal
Suspension	A liquid pharmaceutical form that contains medicinal agents and consists of solid particles dispersed through a liquid phase in which the particles are not soluble.		Oral, topical, ophthalmic, otic
Suspension, liposomal	A liquid preparation consisting of an oil phase dispersed throughout an aqueous phase in such a manner that liposomes are formed.		Oral, topical, ophthalmic, otic
Syrup	An oral solution containing high concentrations of sucrose or other sugars.		Oral
Syrup, extended release	An oral solution containing high concentrations of sucrose or other sugars that is formulated to release the medicinal agents in such a manner to allow a reduction in dosing frequency as compared to that of the medicinal agents presented as a conventional dosage form.	Sustained release, prolonged release, controlled release, timed release	Oral
Tablet	A solid pharmaceutical form that contains medicinal agents and is manufactured by compressing uniform volumes of particles.	Pill, caplet	Oral, sublingual, vaginal
Tablet, chewable	A tablet formulated and manufactured so that it may be chewed, producing a pleasant tasting residue in the oral cavity that is easily swallowed and does not leave a bitter or unpleasant aftertaste.		Oral
Tablet, combined release	A tablet that consists of two or more medicinal agents with different delivery characteristics (e.g. immediate release and extended release).	Tablet, dual release	Oral
Tablet, delayed release	A tablet formulated to release the medicinal agents at any time other than promptly after administration.	Enteric coated	Oral

Dosage Form	Definition	Synonyms	Route of Administration
Tablet, effervescent	An uncoated tablet usually composed of sodium bicarbonate, citric acid and tartaric acid that, when in contact with water, has the capability to release gas, resulting in effervescence.		Oral
Tablet, extended release	A tablet formulated to release the medicinal agents in such a manner to allow a reduction in dosing frequency as compared to that of the medicinal agents presented as a conventional dosage form.	Sustained release, prolonged release, controlled release, timed release	Oral
Tablet, rapid dissolving	A tablet formulated to disintegrate or dissolve in approximately 15 to 30 seconds in the mouth.		Oral
Tea bag, herbal tea	One or more dried plant(s) in an individual bag used to prepare a beverage with therapeutic properties.	Tisane, tea bag	Oral
Tincture	An alcoholic or hydro-alcoholic solution prepared from vegetable materials or from chemical substances.		Oral, topical, otic, ophthalmic
Tisane, loose herb	One or more dried plant(s) contained in a sealed package (for example in a bag or box) used to prepare a beverage with therapeutic properties.	Loose herb, herbal tea	Oral
Tisane, tea bag	One or more dried plant(s) in an individual bag used to prepare a beverage with therapeutic properties.	Tea bag, herbal tea	Oral
Vapour from liquid	A liquid preparation containing medicinal agents converted into a vapour for administration to the lungs for either a local or systemic effect.		Inhalation, nasal
Vapour from solid	A solid preparation containing medicinal agents converted into a vapour for administration to the lungs for either a local or systemic effect.		Inhalation, nasal
Vinegar extract	A type of extract prepared by treating a plant or a plant material, an alga, a bacterium, a fungus or an animal material with vinegar to obtain the desired compounds		Oral
Wafer	A thin slice of material that contains medicinal agents.		Topical, oral
Wipe	A cloth that contains medicinal agents.		Topical

APPENDIX 9: LIST OF ACCEPTABLE ROUTES OF ADMINISTRATION

Route of Administration: The path by which the NHP is brought into contact with the body; for example, oral, topical, nasal. Only one route may be chosen for a product.

Routes of Administration

Buccal: Directed toward the cheek, from within the mouth
Dental: Applied to a tooth or teeth
Inhalation (oral and/or nasal): Into lung tissue (including the bronchi) via the nose or mouth for local or systemic effect (specify nasal and/or oral)
Irrigation: To bathe or flush open wounds or body cavities
Nasal: Into the nose or absorption by the nasal tissue for systemic effect
Ophthalmic: To the external eye
Oral: To or by way of the mouth
Otic: To or by way of the ear
Rectal: Into the rectum
Sublingual: Beneath the tongue
Topical: To a particular spot on the outer surface of the body
Transdermal: Through the dermal layer of the skin to the systemic circulation by diffusion
Vaginal: Into the vagina