

PRODUCT LICENCE APPLICATION FORM
Natural Health Products Directorate

Protected when completed

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

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

PART 1 – APPLICANT AND CONTACT INFORMATION

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

4. Applicant/Company Name*	5. Company Code (If known)
NutriStart Vitamin Company Inc.	

6. Address: Street/Suite/PO Box*			
1988 Woodley Road			

7. City – Town*	9. Province – State*	8. Country*	10. Postal/ZIP Code*
Victoria	BC	CANADA	V8P 1K3

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

11. Name <input checked="" type="checkbox"/> Mr. <input type="checkbox"/> Ms. <input type="checkbox"/> Dr.	12. Title	13. Language preferred:
Surname FITZPATRICK Given Name JON	PRESIDENT	<input checked="" type="checkbox"/> English <input type="checkbox"/> French

14. Company Name (* if different from Applicant/Licensee)	15. Address <u>same as</u> "A" <input checked="" type="checkbox"/>
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16. Street/Suite/PO Box*			
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17. City – Town*	19. Province – State*	18. Country*	20. Postal/Zip Code*
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21. Telephone No.*	Ext.	22. Fax No.	23. E-mail
250-704-1308		250-704-1307	info@nutristart.com

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

24. Contact <u>same as</u> "B" <input type="checkbox"/>	26. Title	27. Language preferred:
25. Name <input checked="" type="checkbox"/> Mr. <input type="checkbox"/> Ms. <input type="checkbox"/> Dr.	President	<input checked="" type="checkbox"/> English <input type="checkbox"/> French
Surname BRIAN Given Name WAGNER		

28. Company Name (*if different from Applicant/Licensee)	29. Address <u>same as</u> "A" <input type="checkbox"/>
NHP Consulting Inc.	

30. Street/Suite/PO Box*			
171 – 5005 Dalhousie Drive, Suite 142			

31. City – Town*	33. Province – State*	32. Country*	34. Postal/Zip Code*
Calgary	Alberta	Canada	T3A5R8

35. Telephone No.*	Ext.	36. Fax No.	37. E-mail
206-201-2786		403-288-1442	brian.wagner@nhpc-research.com

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

38. Contact <u>same as</u> "C" <input checked="" type="checkbox"/>	40. Title	41. Language preferred:
39. Name <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. <input type="checkbox"/> Dr.		<input checked="" type="checkbox"/> English <input type="checkbox"/> French
Surname* _____ Given Name* _____		

42. Company Name (* if different from Applicant/Licensee)	43. Address <u>same as</u> "C" <input checked="" type="checkbox"/>
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44. Street/Suite/PO Box*			
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45. City – Town*	47. Province – State*	46. Country*	48. Postal/Zip Code*
		Canada	

49. Telephone No.*	Ext.	50. Fax No.	51. E-mail
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E. – CONTACT TO WHOM THE PRODUCT LICENCE IS TO BE SENT:	52. As Above: B: <input type="checkbox"/> C: <input checked="" type="checkbox"/> D: <input type="checkbox"/> Not Applicable: <input type="checkbox"/> Name: _____ (check only one box)
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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/Labeling 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 Change to Animal Tissue Form(s)
 Source material of any of its medicinal ingredients Recommended use/purpose
 Addition or substitution of a non-medicinal ingredient not on the NHPD List of Acceptable non-medicinal ingredients Change to or from synthetically manufactured
 Specification Recommended duration of use
 Deletion or modification of risk information on any labels Change to manufacturing information
 Recommended dose

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. Sale under a brand name other than the one(s) originally authorized for the product license
 Change to the common name of any of its medicinal ingredients Change to the proper 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 applicant or Canadian representative.
 Change to the name, address, telephone number, fax number, and/or electronic mail address of the manufacturer, packager, labeller, importer, and distributor. 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	<input checked="" type="checkbox"/> Animal tissue form(s)	#: 1 form(s) in	1
<input checked="" type="checkbox"/> Product licence application form 1	<input type="checkbox"/> Designated Party Authorization form:		
<input type="checkbox"/> Additional pages for Product Information	<input checked="" type="checkbox"/> Label Text	#: 1 form(s) in	1
<input type="checkbox"/> Additional pages for Site Information	<input type="checkbox"/> TPD Label Text (Transitional DIN or Homeopathic DIN)		
<input checked="" type="checkbox"/> Evidence Summary Report: 1	<input checked="" type="checkbox"/> Quality Summary Report:		1
<input checked="" type="checkbox"/> Safety Summary Report: 1	<input type="checkbox"/> 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:	<input type="checkbox"/> Safety	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Quality
	Letter of access(es) enclosed: <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable		
Company #: _____	File #: _____	Submission #: _____	NPN/DIN-HM #: _____
Contains information to support:	<input type="checkbox"/> Safety	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Quality
	Letter of access(es) enclosed: <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable		
Company #: _____	File #: _____	Submission #: _____	NPN/DIN-HM #: _____
Contains information to support:	<input type="checkbox"/> Safety	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Quality
	Letter of access(es) enclosed: <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable		

G. – NHPD MASTER FILE (if applicable)

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

Master File #: _____ Letter of access enclosed: Yes Not Applicable

Contains information to support: Safety only Efficacy only Quality only Complete submission
 Attach separate sheets (same format) if necessary. Number of pages attached: _____

PART 3 – SITE INFORMATION

62. Company Name MANUFACTURER INFORMATION IS NOT BEING SUBMITTED AT THIS TIME.			63. <input checked="" type="checkbox"/> Manufacturer SL# _____ <input type="checkbox"/> Packager SL# _____ <input type="checkbox"/> Labeller SL# _____ <input type="checkbox"/> Importer SL# _____ <input type="checkbox"/> Distributor
64. Number, Street – Suite – PO Box			
65. City			
66. Province – State	67. Country CANADA	68. Postal Code – Zip Code	

62. Company Name			63. <input type="checkbox"/> Manufacturer SL# _____ <input type="checkbox"/> Packager SL# _____ <input type="checkbox"/> Labeller SL# _____ <input type="checkbox"/> Importer SL# _____ <input type="checkbox"/> Distributor
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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: NONE

PART 4 – PRODUCT INFORMATION

70. Primary Brand Name*

PODS PREMIUM II

71. If necessary, attach a separate sheet with other brand names. Number of pages attached: NONE

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.				Quercetin		25 mg		x		x
2.				<i>Rosa canina</i>	Rose Hips Extract	400 mg		x		x
3.				Hesperidin		25 mg		x		x
4.				<i>Arthrospira platensis</i>	spirulina	250 mg		x		x
5.				<i>Palmaria palmata</i>	Dulse Powder	250 mg		x		x
6.				<i>Vitis vinifera</i>	grape seed extract	25 mg		x		x
7.				Choline	choline bitartrate	100 mg		x		x
8.				Inositol		100 mg		x		x
9.				Alpha Lipoic Acid	Alpha Lipoic Acid	25 mg		x		x
10.				Cellulase		2000 FCC/g		x		x
11.				Hemicellulase		1000 FCC/g		x		x
12.				Amyloglucosidase		100 FCC/g		x		x
13.		Fish Oil	2006	Fish Oil		1000 mg		x		x
14.				Amylase		10000 FCC/g		x		x
15.				<i>Medicago sativa</i>	alfalfa juice	75 mg		x		x
16.				<i>Eleutherococcus senticosus</i> root	Siberian Ginseng Extract	100 mg		x		x
17.				<i>Hordeum vulgare</i>	Barley Grass Juice	50 mg		x		x
18.				<i>Fucus vesiculosus</i>	Kelp powder	250 mg		x		x
19.				Protease		5000 FCC/g		x		x
20.				Lipase		1000 FCC/g		x		x
21.				Lactase		1000 FCC/g		x		x
22.				Vitamin A		826 mcg RAE		x		x
23.				Beta Carotene		751 mcg RAE		x		x
24.				Vitamin D		400 IU		x	x	
25.				Thiamine		30 mg	x			x
26.				Riboflavin		30 mg		x		x
27.				Niacinamide		30 mg		x		x
28.				Pyridoxine		30 mg	x			x
29.				Vitamin B12		100 mcg		x		x
30.				Biotin		100 mcg		x		x

31.				Folic Acid		1000 mcg		x		x
32.				Pantothenic Acid		50 mg		x		x
33.				Vitamin E		400 IU		x		x
34.				Vitamin C		500 mg		x		x
35.				calcium		200 mg		x		x
36.				magnesium		200 mg		x		x
37.				copper		1000 mcg		x		x
38.				zinc		15 mg		x		x
39.				manganese		5 mg		x		x
40.				potassium		99 mg		x		x
41.				iodine		100 mcg		x		x
42.				chromium		200 mcg		x		x
43.				selenium		100 mcg		x		x
44.				molybdenum		30 mcg		x		x
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		
	82. Amount	83. Constituent		86. Ratio	87. Quantity Crude Equivalent	Original Material				
							88. Fre sh	89. Dry		
1.				INDICATE SOURCE MATERIAL						
2.				<i>Rosa canina</i>	4:1	1600 mg		x		
3.				INDICATE SOURCE MATERIAL						
4.				<i>Arthrospira platensis</i>						
5.				<i>Palmaria palmata</i>						
6.				<i>Vitis vinifera</i>						
7.				INDICATE SOURCE MATERIAL						
8.				INDICATE SOURCE MATERIAL						
9.				INDICATE SOURCE MATERIAL						
10.				INDICATE SOURCE MATERIAL						
11.				INDICATE SOURCE MATERIAL						
12.				INDICATE SOURCE MATERIAL						
13.	180 120	EPA DHA		WHAT SPECIES OF FISH (BY COMMON NAME) ARE USED FOR THIS?						
14.				INDICATE SOURCE MATERIAL						
15.				<i>Medicago sativa</i>						
16.				<i>Eleutherococcus senticosus</i>	4:1	400 mg		x		
17.				<i>Hordeum vulgare</i>						
18.				<i>Fucus vesiculosus</i>						
19.				INDICATE SOURCE MATERIAL						
20.				INDICATE SOURCE MATERIAL						
21.				INDICATE SOURCE MATERIAL						
22.				Palmitate						

23.			<i>Dunaliella salina</i> algae					
24.			sheep's wool					
25.			Thiamine HCl					
26.			INDICATE SOURCE MATERIAL					
27.			INDICATE SOURCE MATERIAL					
28.			INDICATE SOURCE MATERIAL					
29.			INDICATE SOURCE MATERIAL					
30.			INDICATE SOURCE MATERIAL					
31.			INDICATE SOURCE MATERIAL					
32.			INDICATE SOURCE MATERIAL					
33.			INDICATE SOURCE MATERIAL					
34.			calcium ascorbate					
35.			coral calcium, calcium citrate					
36.			magnesium oxide, magnesium citrate					
37.			copper chelate					
38.			zinc citrate					
39.			manganese chelate					
40.			potassium chelate					
41.			potassium iodide					
42.			chromium GTF					
43.			INDICATE SOURCE MATERIAL					
44.			molybdenum chelate					

91. Attach separate sheets (same format) if necessary. Number of pages attached: NONE

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.		silica	thickening agent		x
2.					
3.					
4.					
5.					
6.					
7.					

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.			

C. – INGREDIENT(S) USED IN PROCESSING

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

PART 4 – PRODUCT INFORMATION

D. – RECOMMENDED CONDITIONS OF USE

102. Recommended Use or Purpose*

Works in conjunction with other antioxidants to enhance performance in athletes; may be used in conjunction with other antioxidants to maintain health. Is an antioxidant for the maintenance of good health. May help relieve knee pain in persons with knee or hip osteoarthritis. May help reduce symptoms of chronic venous insufficiency (CVI). Promotes higher metabolism in healthy adults. Has anti-inflammatory properties to aid with allergy symptoms in healthy adults, as well as fighting respiratory infections. Promotes immune functioning in healthy adults and possesses anti-viral properties. Source of essential nutrients (choline, iodine) for the maintenance of good health. Helps improve the lipid profile of individuals (including lowering cholesterol), thereby promoting cardiovascular health. Helps reduce the damaging effects of stress. Provides lipotropic factors (lipase, inositol, choline) for the maintenance of good health. May aid in digestion of various food (including vegetables, fruits, carbohydrates, lipids). Source of omega-3 fatty acids for the maintenance of good health. Source of EPA and/or DHA for the maintenance of good health. Helps support cognitive health / brain function. Helps maintain / support cardiovascular health. Helps to reduce serum triglycerides / triacylglycerols. In conjunction with conventional therapy, helps reduce the pain of rheumatoid arthritis.

103. Dosage Form (one only)*

PACK (“POD”) with capsules

104. Sterile* Yes No

105. Route of Administration*

ORAL

106. Duration of Use (if any)

NONE

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.)		
ADULTS	1	POD	DAILY	WITH MEALS

Risk Information

113. Cautions and Warnings*

Consult a health care practitioner prior to use if you are also taking prescription drugs that are P-glycoprotein substrates, such as vincristine and digoxin. This product contains phenylalanine. If this product is taken for a period longer than three weeks, it is advised to consume a vitamin E supplement at the same time. Avoid prolonged exposure to sources of ultraviolet radiation (e.g. sunlight, black light, tanning salons or other tanning devices). Consult a health care practitioner prior to use in the following circumstances: if you have high blood pressure, if you are undergoing hormonal replacement therapy, if you have a hormone sensitive condition (breast cancer, uterine cancer, endometriosis), or if you have diabetes.

114. Contraindications*

Do not take this product in the following circumstances: if you are pregnant or breastfeeding, if you have (or have had) a thyroid condition (such as hyperthyroidism), if you have (or have had a history of) liver problems (such as hepatitis), if you have a thiamine deficiency, if you have a history of systemic lupus erythematosus, or if you have liver disease. Do not take this product if you are taking certain medication, specifically: daunomycin thyroid medications corticosteroids, cyclosporine, blood thinners, birth control medication, MAOIs, or heart medication.

115. Known Adverse Reactions*

[none]

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:

- 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**
- 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 Official¹ (print)*

Jon Fitzpatrick

117. Signature*

118. Date*

| y | y | y | y | m | m | d | d |

If the signing official is a third party acting on behalf of the Senior Official of the applicant company designated in Part 1 of the application, a designated Party Authorization form must be signed by the Senior Official and filed with the complete application.