

# 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	

### PART 1 – APPLICANT AND CONTACT INFORMATION

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

4. Applicant/Company Name* NutriStart Vitamin Company			5. Company Code (If known) <b>16159</b>
6. Address: Street/Suite/PO Box* 1988 Woodley Road			
7. City – Town* Victoria	9. Province – State* BC	8. Country* Canada	10. Postal/ZIP Code* 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. Surname <b>FITZPATRICK</b> Given Name <b>JON</b>		12. Title <b>President</b>	13. Language preferred: <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"/>
16. Street/Suite/PO Box*			
17. City – Town*	19. Province – State*	18. Country*	20. Postal/Zip Code*
21. Telephone No.* 250-704-1308	Ext.	22. Fax No. 250-704-1307	23. E-mail 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 <b>President</b>	27. Language preferred: <input checked="" type="checkbox"/> English <input type="checkbox"/> French
25. Name <input checked="" type="checkbox"/> Mr. <input type="checkbox"/> Ms. <input type="checkbox"/> Dr. Surname <b>WAGNER</b> Given Name <b>BRIAN</b>			
28. Company Name (*if different from Applicant/Licensee) NHP Consulting Inc.			29. Address <u>same as</u> "A" <input type="checkbox"/>
30. Street/Suite/PO Box* 171 – 5005 Dalhousie Drive, Suite 142			
31. City – Town* Calgary	33. Province – State* Alberta	32. Country* Canada	34. Postal/Zip Code* T3A5R8
35. Telephone No.* 403-202-2408	Ext.	36. Fax No. 1-888-875-8826	37. E-mail 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: <input checked="" type="checkbox"/> English <input type="checkbox"/> French
39. Name <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. <input type="checkbox"/> Dr. Surname* _____ Given Name* _____			
42. Company Name (* if different from Applicant/Licensee)			43. Address <u>same as</u> "C" <input checked="" type="checkbox"/>
44. Street/Suite/PO Box*			
45. City – Town*	47. Province – State*	46. Country* <b>Canada</b>	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: <input type="checkbox"/> C: <input checked="" type="checkbox"/> D: <input type="checkbox"/>
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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  NO SITE INFORMATION IS BEING SUBMITTED AT THIS TIME, WHICH IS TECHNICALLY NOT REQUIRED FOR A HYPOTHETICAL FORMULATION.	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	
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# _____	
64. Number, Street – Suite – PO Box	<input type="checkbox"/> Packager SL# _____	
65. City	<input type="checkbox"/> Labeller SL# _____	
66. Province – State	<input type="checkbox"/> Importer SL# _____	
67. Country	<input type="checkbox"/> Distributor	
68. Postal Code – Zip Code		
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65. City	<input type="checkbox"/> Labeller SL# _____	
66. Province – State	<input type="checkbox"/> Importer SL# _____	
67. Country	<input type="checkbox"/> Distributor	
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\*

# EnergyStart

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

### A. – MEDICINAL INGREDIENT(S) per capsule

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.				<i>Zingiber officinale Roscoe</i>	Ginger	41.66 mg		x		x
2.				<i>Rhodiola rosea</i>	Rhodiola	37.5 mg		x		x
3.				<i>Withania somnifera</i>	Ashwagandha Standardized Extract	83.3 mg		x		x
4.				<i>Schisandra chinensis</i>	Schizandra Standardized Extract	166.67 mg		x		x
5.				Royal Jelly	Royal Jelly	83.3 mg		x	x	
6.				<i>Polygonum multiflorum</i>	Fo Ti (Ho Shou Wu)	166.67 mg		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. Fres h	89. Dry		
1.	5%	Gingerol	root/rhizome	5:1	208.3 mg			x		
2.	3%	rosavins	root/rhizome							
3.			root/rhizome							
4.			berries/fruit							
5.	5%	???								
6.			fruiting body							

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.		microcrystalline cellulose	capsule constituent		x
2.		water	capsule constituent		x

97. Ingredient No.	98. Standard or Grade	99. Quantity	100. Source Information (if more than one enter on new line)
1.			
2.			

### 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\*

Ginger oil may support healthy immune system functioning and offer protection against oxidative stress for the maintenance of good health. Acts as an adaptogen reducing the damaging effects of stress on the body, while promoting immune functioning. Helps reduce inflammation in non-specific inflammatory conditions. Supports adaptation to stress for general health maintenance in healthy adults. Promotes energy and feelings of rejuvenation in men, specifically by strengthening muscles and bone marrow and promoting semen quality. Helps to lower blood cholesterol levels in people with elevated cholesterol. Promotes antioxidant status for increased protection against oxidative stress.

103. Dosage Form (one only)\*

CAPSULE

104. Sterile\*  Yes  No

105. Route of Administration\*

ORAL

106. Duration of Use (if any)

4 WEEKS

#### 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	2	CAPSULES	2 x DAILY	ENERGYStart should be taken for 2 to 4 weeks, (two capsules twice daily). As is the case with most herbal formulas, ENERGYSTART is most effective when taken between meals with a liquid.

#### Risk Information

113. Cautions and Warnings\*

Consult a health care practitioner prior to use in the following circumstances: if abdominal discomfort or heartburn or an irritant effect in the mouth and throat persists after taking the product, if you are currently taking prescription medication (including blood thinners, alcohol or other sedatives), if you are allergic to bee products (this product contains bee saliva), if you have gallstones, or if you have a blood coagulation disorder. If you are allergic to bee products or experience severe allergic reaction that you think are caused by this product (such as breathing problems or tightness in your throat or chest, chest pain, skin hives, rash, itchy or swollen skin), discontinue use and consult a health care practitioner immediately.

114. Contraindications\*

Do not take this product if you are pregnant or breastfeeding.

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 Official<sup>1</sup> (print)\*

Jon Fitzpatrick

117. Signature\*

118. Date\*

y	y	y	y	m	m	d	d
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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.