Health Canada Santé Canada

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Appendix: Temporary Marketing Authorization Submission Form

May 2013

Food Directorate

Health Products and Food Branch

Canada

Appendix: Temporary Marketing Authorization Submission Form

This Temporary Marketing Authorization (TMA) Submission Form should be used to help ensure that a TMA submission is complete and to support an efficient and timely review of the application. Please print or replicate this form, and complete and send it following the instructions below.

Instructions
Part A - Contact information
Part B – Product information
Part C – Product composition
Part D – Detailed information on this product
Part E- Attestation

INSTRUCTIONS

- Refer to the instructions and to the identified sections of the *General Guidance Document for Temporary Marketing Authorization for Foods* provided within this form for help in filling in the required information.

- It is acceptable to indicate N/A for sections that are not applicable to the product. Missing information will be considered as an incomplete submission and may slow the evaluation and approval of your product.

- Fill out one form for **each product** and attach a copy of the proposed label for that product.

- Send the completed form(s) as an attachment to: smiu-ugdi@hc-sc.gc.ca . Enter "*Temporary Marketing Authorization Letter (TMAL) request*" as the subject line of the email. The completed forms can also be faxed to 613-946-4590, with attention to the Submission Management and Information Unit.

- A fillable PDF version of this form is available upon request; contact smiu-ugdi@hcsc.gc.ca.

PART A - CONTACT INFORMATION

A.1. COMPANY INFORMATION

Company name:

Company address (street number, street name):

City: Province/State:

Postal Code/Zip Code: Country:

Name of contact person:

Phone number (include extension):

Other phone number: Fax number:

Email address:

A.2. CONSULTANT INFORMATION (IF APPLICABLE)

□ Designated Party Authorization (DPA) form provided or attached

Consulting firm name:

Company address (street number, street name):

City: Province/State:

Postal Code/Zip Code: Country:

Contact person:

Phone number (include extension):

Other phone number: Fax number:

Email address:

PART B - PRODUCT INFORMATION

1. Have you previously submitted an application for this product to the Natural Health Products Directorate?

Yes □ No □

If you answered 'yes', please enter:

1.a. Natural Product Number (NPN) (if applicable):

1.b. Exemption Number (EN) (if applicable):

1.c. Product License Application (PLA) (if applicable):

2. Food's brand name:

3. Serving size (include unit):

4. Container/Package size (include unit):

5. Food format (Please specify, for example, beverage, bar, powder):

6. Maximum number of container(s)/serving(s) not to be exceeded per day (if applicable):

7. Intended target population (if any):

8. Enter the proposed quantity of food to be sold (see section 2.2.5 of the General Guidance Document for Temporary Marketing Authorization for Foods). For example, 10,000 units of 355 ml cans a year for the TMA time period.

9. Other Remarks on proposed quantity, if applicable:

10. List the proposed area designated for such sale (see section 2.2.7 of the General Guidance Document for Temporary Marketing Authorization for Foods). For example, specific province or territory, or national distribution.

PART C - PRODUCT COMPOSITION

(see section 2.2.2 of the General Guidance Document for Temporary Marketing Authorization for Foods)

INSTRUCTIONS: The following information is required for ALL ingredients. Refer to the caption at bottom of the table for clarifications on the marked headers (a-e). This table is provided as an example. Please replicate it and attach to your submission.

State the serving size (quantity and unit) on which ingredient quantities below are based on (example: 250 mL): _____

Ingredient #	Ingredients		Type of ingredient[a] (Additive, botanical/herbal, flavouring, microbial, novel, nutrient, other)	Purpose of ingredient[b]	Quantity[c] (amount, unit)		Component of ingredient[d] (e.g., active ingredient)		Source/Origin of ingredient[e] (If more than one, enter on new line)	Extract (if applicable)				
	Proper name	Common name			Amt	Unit	%	Name		Ratio	Qty Crude Equitv Amt	Qty Crude Equitv Unit	Original Material (Fresh, Dry, NA)	Method
	Example: Vitis vinifera	Grape seed extract	Herbal	Antioxidant	5	mg	80	Proanthocyanidin	Seed	4:1	40	mg	Dry	Water extraction
1														
2														
3														
4														
5														
6														

a- **Type of Ingredient:** Select one from options provided. If 'Other', clarify the type of ingredient under the 'Purpose of ingredient' column
b- **Purpose of Ingredient:** Example: sweetener, colour, emulsifier.
c- **Quantity Unit:** State in System International (SI) unit or, standard scientific abbreviations (eg: I.U., µg, CFU)
d- **Component of Ingredient:** Amount of active component per listed ingredient
e- **Source/origin of ingredient:** Example: animal and tissue, plant and plant part (root, seed, leaf), synthetic

PART D - DETAILED INFORMATION ON THIS PRODUCT

1. Describe the purpose for which the TMA of the food is required (see section 2.2.1 of the General Guidance Document for Temporary Marketing Authorization for Foods) (Max. 900 characters).

2. Provide a brief description of the food (see section 2.2.2 of the General Guidance Document for Temporary Marketing Authorization for Foods) (Max. 900 characters).

3. List all proposed claims (for example, nutrient content claims, health claims) associated with the food. Also include the amount per stated serving size of the nutrient associated with the claim (s).

State the serving size (quantity and unit) on which the nutrients below are based on (example: 250 mL):

Claim	Nutrient	Amount and unit of nutrient per stated serving size

4. List any caution statements or labelling instructions used to inform and mitigate risks to consumers. Answer each section below, where applicable:

(a) Direction of Use:

(b) Caution & Warning:

(c) Contraindications:

(d) Known Adverse Effects:

5. Provide a description of any proposed variation from the requirements of the Food and Drug Regulations (FDR) (see section 2.2.3 of the General Guidance Document for Temporary Marketing Authorization for Foods) (Max. 900 characters).

6. Provide adequate data to show that the use of the ingredients used in the food and/or the food will not be detrimental to the health of the purchaser or user, if applicable (see section 2.2.4 of the General Guidance Document for Temporary Marketing Authorization for Foods). Attach complete references to email along with this form. Provide a rationale if data is not available (Max. 900 characters).

PART E – ATTESTATION

□ I attest that, to the best of my knowledge, the information provided in this submission is true and correct. I understand that Health Canada may request additional information to substantiate the statements made in this declaration.

Attester's name:

Attester's title:

Attester's signature:

Date signed (yyyy-mm-dd):