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# Category Specific Guidance for Temporary Marketing Authorization

## Caffeinated Energy Drinks

December 2013

Food Directorate

Health Products and Food Branch



Canada 

## Table of Contents

<b>SUMMARY</b> .....	4
<b>1.0 Introduction</b> .....	<b>5</b>
1.1 Scope .....	5
1.2 Administrative Matters .....	6
1.2.1 TMA Application Process .....	8
<b>2.0 TMA Research</b> .....	<b>8</b>
2.1 Research .....	8
2.2 Reporting Consumption Incidents .....	9
<b>3.0 Guidance on Eligibility for a TMA for CEDs</b> .....	<b>10</b>
3.1 Vitamins, Mineral Nutrients, and Amino Acids .....	11
3.1.1 Minimum Levels .....	11
3.1.2 Maximum Levels .....	11
3.1.3 Methods for Setting Maximum Levels.....	12
3.1.4 Maximum Levels not Specified.....	13
3.1.5 Vitamins or Mineral Nutrients not Acceptable for Addition .....	14
3.1.6 Vitamins or Mineral Nutrients not Recommended for Addition .....	14
<b>4.0 Food Additives, Flavours, Herbal Ingredients and Novel Foods as Ingredients in CEDs</b> .....	<b>14</b>
4.1 Food Additives .....	14
4.2 Food Flavours .....	15
4.3 Herbal Ingredients.....	15
4.4 Novel Foods.....	16
<b>5.0 Labelling, Advertising and Claims</b> .....	<b>16</b>
5.1 Advertising .....	17
5.2 Reference Amount, Serving Size and Container Size .....	17
5.3 Required Statements.....	18
5.3.1 Quantitative Declaration of Caffeine Content .....	18
5.3.2 Qualitative Declaration of Caffeine.....	18
5.3.3 Caution Statements .....	19
5.3.4 Product Identification .....	19
5.3.5 Quantitative Declaration of Ingredients Other than Caffeine .....	19
5.3.6 Other Required Information .....	21
5.3.7 Placement of Required Statements.....	21
5.3.8 Legibility and Prominence of Required Statements .....	21
5.4 Priority Allergens, Gluten Sources, and Sulphites .....	22
5.5 Voluntary Statements .....	22
5.5.1 Claims Related to Physical Performance .....	23

5.5.2 *Claims Related to General or Specific Health Benefits* ..... 23

5.5.3 *Calorie-Free and Sugar-Free Claims*..... 24

5.5.4 *Placement and Prominence of Voluntary Statements* ..... 24

5.6 Sample Label..... 24

**Appendix: Reference List of Ingredients**..... 27

### Summary

In October 2011, Health Canada (the Department) announced its intent to transition caffeinated energy drinks (CEDs) from the natural health products regulatory framework to the food regulatory framework. The first version of this guidance document was developed in March 2012, in the context of the transition of CEDs to the food regulatory framework as a means to clarify the Temporary Marketing Authorization (TMA) requirements for CEDs. Given that the transition of CEDs was completed in December 2012, this version of the guidance document has been updated to reflect that change as well as certain sections as indicated below. The updated guidance document replaces the Category Specific Guidance for Temporary Marketing Authorization - Caffeinated Energy Drinks dated March 2012 and is effective immediately.

As there are some changes to the maximum levels of some vitamins, Health Canada will work with companies holding a TMA that is affected, as well as companies with a product in development which may now be out of compliance with this guidance, to bring the product into compliance.

This guidance document applies to all pre-packaged, ready-to-consume, predominantly water-based CEDs containing caffeine from all sources between 200 and 400 ppm sold in Canada.

The main revisions to the guidance are as follows:

- Section 1.2 - Administrative Matters: Information on the transition of CEDs to the food regulatory framework has been removed;
- Section 3.0 – Guidance on Eligibility for a TMA for CEDs: Additional eligibility criteria have been included;
- Sections 3.1.2 - Maximum Levels and 3.1.4 - Maximum Levels not Specified: Maximum permitted levels of addition for niacinamide and pantothenic acid have been revised;
- Section 5.1 - Advertising: Clarification around the communication of risk information in advertising is provided;
- Section 5.2 - Reference Amount, Serving Size and Container Size: Criteria for multi-serving containers have been clarified.
- Section 5.3.4 – Product Identification: Labelling criteria for product identification have been included.

### 1.0 Introduction

In recent years, an increasing number of CEDs have been introduced into the Canadian marketplace. Although Canada does not have a standard of identity for CEDs, these products typically refer to beverages containing caffeine in combination with other ingredients such as taurine, glucuronolactone and B vitamins. These products may also contain minerals, various herbal ingredients and other bioactive ingredients. CEDs generally feature health claims related to their capacity to restore energy and alertness in the individual consuming the product. Since there are specific provisions limiting the addition of caffeine, vitamins, mineral nutrients and amino acids to foods outlined in the *Food and Drug Regulations*, manufacturers and distributors of CEDs previously sought and gained market access as natural health products (NHPs).

Health Canada has determined, based on public perception and history of use, product representation to consumers and product format, in accordance with the [classification guidance](#) outlined on its website, that CEDs fit the definition of a food. Subsequent to this determination, in October 2011, the Minister of Health announced the Department's intention to classify and regulate CEDs as foods.

While there are no immediate safety concerns, there remain a number of outstanding information gaps needing to be addressed in order to develop and finalize the regulatory requirements for these products. Examples include consumption patterns of CEDs in the dietary context as food and the effectiveness of labelling as a risk mitigation tool. A TMA (refer to sections B.01.054, B.01.055 of the *Food and Drug Regulations*) was determined to be the most appropriate regulatory tool to gather the necessary information while allowing these products to be marketed temporarily under specific conditions.

**The purpose of this document** is to outline the eligibility criteria for TMAs with respect to CEDs. These requirements were developed based on information available as a result of a risk assessment conducted by Health Canada. It is important to note that these are temporary requirements while Health Canada gathers information to address a number of information gaps, conducts a more detailed assessment of these products and evaluates the effectiveness of risk management tools. Information received through research requirements under Temporary Marketing Authorization Letters (TMALs) will facilitate this analysis. As a result, these requirements are subject to change as new information becomes available and should not be construed as final regulatory requirements for these products.

This document should be read together with the [General Guidance Document for Temporary Marketing Authorization for Foods](#) and other applicable provisions of the *Food and Drugs Act* and the *Food and Drug Regulations*, along with other applicable food related legislation and regulations.

### 1.1 Scope

#### Products included for the purposes of this guidance document

CEDs eligible for a TMA are pre-packaged, ready-to-consume, predominantly water-based caffeinated beverages. Caffeine from all sources is at levels between 200 and 400 ppm (mg/L) and these products typically contain added vitamins and amino acids.

### **Products not included in the scope of this guidance document**

Caffeinated products that are not consumed or perceived as foods will continue to be classified as NHPs. For example, many products termed “Energy Shots” are distinguished from foods by their smaller volumes and product representation. Health Canada has set the upper limit for the volume of an energy shot at 90 mL; therefore, caffeinated products that are pre-packaged, ready-to-consume, containing 90 mL or less, and meant to be consumed in a single dose, shall be classified as NHPs. The typical container size for most food beverages is 125 mL or greater; therefore, CEDs with a volume of 125 mL or greater shall be classified as a caffeinated energy drink and be regulated as a food. Caffeinated products with a volume greater than 90 mL but less than 125 mL will be classified on a product-by-product basis which will take into account product representation.

CEDs dispensed via fountain machine systems are not eligible for a TMA as they are not pre-packaged. The manner in which these products are sold to consumers pose a significant challenge to informing consumers of the product’s caffeine and vitamin and mineral content. This does not allow for the consumer to be aware of the caffeine or vitamins and mineral nutrients they are consuming and could lead to overconsumption. Moreover these types of products lack the label information as set out in this guidance document (for example, amount of caffeine from all sources, caution statement against mixing CEDs with alcohol, maximum containers or servings not to exceed per day). As well, children and pregnant and/or breastfeeding women would not be informed that these products are not intended for them due to the potential risk they present for these vulnerable populations. While these products are considered food, Health Canada has determined that this format presents an unacceptable risk due to lack of label information and potential for overconsumption.

Health Canada will continue to apply the [classification guidance](#) outlined on its website on a product-by-product basis to determine whether a product is classified as a food or a NHP.

## **1.2 Administrative Matters**

CEDs are subject to all relevant requirements applicable to food products, including the provisions of the *Food and Drugs Act* and its Regulations and the *Consumer Packaging and Labelling Act and Regulations* except for those requirements of the *Food and Drug Regulations* which have been exempted under the TMAL. It is the responsibility of the manufacturer or distributor to ensure that marketed food products are in compliance with all applicable statutory and regulatory requirements other than those which are subject of the TMA. Additional

requirements have been set to alert the consumer to the uniqueness of these products and to help ensure their safe use as foods. These include:

- Compositional requirements;
- Labelling, advertising and marketing requirements;
- Prohibition of alcohol content; and
- Consumption incident reporting.

Further details are outlined in the following sections of this guidance document.

TMALs are regulatory instruments that allow for non-compliant foods that meet all the requirements of a TMA to be sold before the regulatory amendments are made. The purpose of the TMA is to gather specific data that will support an amendment to the *Food and Drug Regulations*. Therefore, as a condition of the TMA, the manufacturer or distributor is required to gather such data, in a manner agreed upon with Health Canada in advance, and submit it to Health Canada within a specified time frame. The specific details of the research protocol required for the TMAL may be finalized after the TMAL is issued and can be appended to the TMAL at a later date, once an agreement is reached between Health Canada and the petitioner. Health Canada may revoke a TMA should a manufacturer or distributor fail to supply the required data that addresses the identified knowledge gaps associated with the research protocol.

Health Canada will issue TMALs for products that meet the compositional and labelling requirements, which include conditions for the level of caffeine from all sources, for levels of added vitamins, minerals and amino acids, and for which there are no unapproved novel ingredients or food additives. The product must comply with the conditions outlined in the TMAL including prohibiting the advertising, marketing, or promotion of CEDs to children and pregnant and/or breastfeeding women. For the purposes of this guidance, children are defined as 12 years of age and younger.

A [list of authorized products](#), those that have received TMAs, is available on Health Canada's website. This list is updated regularly as TMALs are issued. The information is posted in accordance with the *Privacy Act*. In addition to the standard requirements for TMAs, companies are required to report annual data on consumption incidents (refer to section 2.2).

If a petitioner wishes to make a change to the conditions of a TMAL after it has been issued, an amendment to the TMAL is required. Petitioners should submit requests using the TMA application process (refer to section 1.2.1).

### **Enforcement**

Health Canada's Food Directorate and the Canadian Food Inspection Agency will work collaboratively to identify potential compliance issues and determine the appropriate compliance and enforcement actions that may be taken. Health Canada may revoke a TMA if it is determined that the conditions of the TMA have been violated.

Note that the Canadian Food Inspection Agency may take enforcement action, which may include recall of the products that are the subject of a TMAL, should Health Canada identify any significant health risks or contraventions to Sections 4 or 5(1) of the *Food and Drugs Act*.

### 1.2.1 TMA Application Process

Manufacturers or distributors are advised to follow the application process outlined in the document [General Guidance Document for Temporary Marketing Authorization for Foods](#) while also making reference to the specific requirements for CEDs laid out in the sections below.

Submissions should be delivered to Health Canada as outlined in the document [General Guidance Document for Temporary Marketing Authorization for Foods](#).

A submission may be sent electronically to the following address: [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca). Please use the words "TMA application – Caffeinated Energy Drinks" in the subject line.

If delivering a submission by mail, three hard copies must be sent to the address below:

Submission Management and Information Unit  
Food Directorate  
Health Products and Food Branch, Health Canada  
251 Sir Frederick Banting Driveway  
Postal Locator 2202E  
Ottawa, Ontario, Canada, K1A 0K9

For further guidance, please contact Health Canada at [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca), using "Caffeinated Energy Drinks" as the subject.

## 2.0 TMA Research

### 2.1 Research

Health Canada conducted a scientific assessment<sup>1</sup> of the potential hazards associated with and exposure to the common ingredients found in CEDs, such as caffeine and vitamins. Based on the

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<sup>1</sup> Rotstein et al. Energy Drinks: An Assessment of the Potential Health Risks in the Canadian Context. *International Food Risk Analysis Journal*. 2013; 3(4).

maximum levels of caffeine and vitamins and minerals as stipulated within this guidance document, there are no immediate health and safety issues associated with CEDs currently available on the Canadian market place if consumed as recommended; however, Health Canada has concluded that a number of data gaps must be addressed to support its efforts to regulate CEDs as a food and to appropriately manage potential health risks associated with these products.

To address these gaps, Health Canada requires data on: Canadian CED consumption patterns in order to better estimate exposure to caffeine and other ingredients found in these beverages; and data on consumers' understanding and use of label information as a risk management tool.

As a condition of the TMA, details of the research to be conducted during the temporary marketing period must be submitted to Health Canada for review. Research and data collection for CEDs must be targeted to address the data gaps mentioned above, so that information can be generated that will be relevant and supportive of an amendment to the *Food and Drug Regulations*. Agreement between Health Canada and the petitioner must be reached on the research protocol prior to the implementation of any studies.

Due to the large number of CEDs that currently have gained market access under a TMA, as well as new CEDs that are expected to gain market access via the same means, and the fact that many of the data gaps are common to all CEDs, it may be more efficient for some of the research to be conducted collectively (via a trade organization, representative of the sector). However, additional product specific information (for example, sales volume information) will be required to be provided by individual manufacturers or distributors.

### **2.2 Reporting Consumption Incidents**

A consumption incident is characterized by the fact that a causal relationship between the consumption of a CEDs and the occurrence of an adverse effect is suspected. Manufacturers or distributors of CEDs are required to undertake consumption incident reporting as a condition of their TMAs. Consumption incident reports must be submitted to Health Canada annually. If there are no incidents within the year, this information also needs to be provided to Health Canada. Any serious consumption incidents should be reported to the Canadian Food Inspection Agency on an expedited basis, ideally within two weeks.

Health Canada has developed a guidance document and form to assist with reporting information on consumption incidents. Additional details on reporting consumption incidents are outlined in the *Guidance Document for Industry: Annual and Ad hoc Consumption Incident Reporting* and the associated form (to be posted at a later date).

Completed annual consumption incident reporting forms are to be sent to:

Submission Management and Information Unit

Food Directorate  
Health Products and Food Branch, Health Canada  
251 Sir Frederick Banting Driveway  
Postal Locator 2202E  
Ottawa, Ontario, Canada, K1A 0K9  
Email: [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca)

### 3.0 Guidance on Eligibility for a TMA for CEDs

To be eligible for a TMA, CEDs must meet the following criteria:

- Shall contain a concentration of caffeine no less than 200 ppm (mg/L) and no more than 400 ppm;
- For a single-serving container, the maximum amount of caffeine shall not exceed 180 mg, per container. Similarly, for a multi-serving container, the maximum level of caffeine shall not exceed 180 mg, per serving (500 mL). Refer to section 5.2 regarding serving size and container size;
- Shall not contain alcohol;
- Shall not contain singly or in combination, 25% or more fruit and/or vegetable juice, puree or pulp, as consumed;
- Shall not include the word “juice”, “puree” or “pulp” on the label other than as required in the list of ingredients;
- Shall not be represented as flavoured water or flavoured sweetened water;
- Shall not be represented for hydration and/or electrolyte replacement before, during or after physical activity;
- Shall not be dairy-based beverages, soy beverages, rice beverages, almond beverages, and similar plant beverages;
- Shall not contain non-compliant food additives, apart from caffeine (refer to section 4.1);
- Shall not contain unapproved novel ingredients (refer to section 4.4); and
- Shall not be marketed towards children.

### 3.1 Vitamins, Mineral Nutrients, and Amino Acids

In order to be eligible for a TMA, minimum and/or maximum levels for certain vitamins, minerals and amino acids must be respected. **It should be noted that these maximum levels are not intended as recommended levels for addition.** At the present time, the maximum levels are established as daily maximums and, as stated in section 5.3.3, below, companies are required to include a cautionary statement on their labels stating the maximum number of containers/servings that should not be exceeded daily.

It is important that companies take into account any data they have on typical patterns of consumption of CEDs and use that information to determine whether, and to what levels, to add vitamins, mineral nutrients or amino acids to their products in order to reduce the likelihood that consumers will have intakes above the daily maximum levels set for CEDs. The research conducted through the TMA is expected to help determine the usual and upper levels of intake of these products as well as the effectiveness of the label caution statement indicating the maximum number of containers/servings that should not be exceeded daily. Once the data are available, maximum levels of addition may be set on a per reference amount or per “reasonable daily intake” basis. The research will also help to inform a decision whether there is a need to retain the caution statement. Note that the nutrients listed and their maximum levels are subject to change based on future review as new evidence becomes available. If a petitioner wishes to pursue a TMA for a CED that contains nutrients not identified in this guidance, an appropriate rationale for its composition must be provided for Health Canada’s review.

#### 3.1.1 Minimum Levels

When vitamins and minerals nutrients are added to CEDs they should be added at a minimum of 5% of the Daily Value (DV), per reference amount and/or per serving of stated size (refer to Table I in section D.01.013 and Table I in section D.02.006 of the *Food and Drug Regulations*). This is to ensure that the product contains a sufficient amount of the nutrient so as not to be misleading when the product is consumed as a food.

#### 3.1.2 Maximum Levels

Daily maximum levels have been established for certain vitamins, minerals and amino acids to help ensure that their addition to CEDs does not contribute to excessive intakes.

In order to be considered eligible for a TMA, CEDs should provide no more than the daily maximum levels for the ingredients outlined in the table below. In order to determine the maximum number of containers or servings in the caution statement (refer to section 5.3.3), the daily maximum levels should be taken into consideration.

<b>Vitamin/ Mineral Nutrient</b>	<b>Daily maximum levels for CEDs</b>
Niacinamide	126 mg
Riboflavin	27 mg
Thiamine	5 mg
Vitamin B <sub>6</sub>	14 mg
Vitamin B <sub>12</sub>	25 mcg
Vitamin C	276 mg
Vitamin E	141 mg
Calcium	225 mg
Magnesium	25 mg
Phosphorus	364 mg
Potassium	350 mg
<b>Other ingredients</b>	
Taurine	3000 mg

### 3.1.3 Methods for Setting Maximum Levels

The approach used to establish the daily maximum levels varied depending on the availability of a Tolerable Upper Intake Level (UL). Dietary intake data was taken from the Canadian Community Health Survey, Cycle 2.2, Nutrition 2004.

#### **Vitamin B<sub>6</sub>, C, E, Calcium and Phosphorus**

Vitamin B<sub>6</sub>, vitamin C, vitamin E, calcium and phosphorus all have a UL, from the Institute of Medicine (IOM). The daily maximum level for these nutrients was calculated by subtracting the 90<sup>th</sup> percentile of dietary intake plus a buffer calculated using a UL/Recommended Dietary Allowance (RDA) or Adequate Intake (AI) ratio from the UL (using data for adolescents 14-18 years). This daily maximum level was then divided by five based on the assumption that an individual could consume up to five different types of supplemented foods in a day.

#### **Niacinamide**

The maximum level was calculated using the UL for adolescents 15-17 years (700 mg) from the European Commission Scientific Committee on Food and using the same method applied for other nutrients with a UL (vitamin B<sub>6</sub>, C, E, calcium and phosphorus).

### **Riboflavin, Thiamine and Vitamin B<sub>12</sub>**

There is no UL for riboflavin, thiamine or vitamin B<sub>12</sub>. The daily maximum levels were set based on evidence presented in the Dietary Reference Intake (DRI) report using a threshold for maximum absorption, a level above which absorption of the nutrient decreases significantly.

### **Magnesium and Potassium**

There is no UL for potassium and the UL for magnesium concerns only magnesium from supplements. The maximum level of addition is set at 10% of the Daily Value (DV). A cautious approach is warranted given:

- The potential for toxicity for magnesium when added to beverages (laxative effect when not ingested with solid food);
- The increased use of potassium salts to replace sodium; and
- The potential for severe adverse effects with potassium in susceptible individuals (hyperkalemia with people taking common medications and with renal problems).

### **Taurine**

The Natural Health Products Taurine Abbreviated Labelling Standard was used to establish the daily maximum level at 3000 mg. A review article published by SHAO and Hathcock<sup>2</sup> in 2008 concluded that the Observed Safe Level (OSL) risk assessment for taurine indicates that based on the available published human clinical trial data, the evidence for the absence of adverse effects is strong for taurine at supplemental intakes up to 3 g/d in adults. They also concluded that no adverse effects were observed or reported in the reviewed studies using 6 g/d, but the relatively small sample sizes and short duration of these studies argue against their use for identification of an OSL.

#### **3.1.4 Maximum Levels not Specified**

##### **Pantothenic acid**

Given the limited scientific data available, a formal maximum level for pantothenic acid has not been established by Health Canada for CEDs. At this time, Health Canada does not have any health and safety concerns with the addition of pantothenic acid to CEDs at levels up to 100 mg/day.

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<sup>2</sup> Shao A, Hathcock JN. Risk assessment for the amino acids taurine, L-glutamine and L-arginine. Regul Toxicol Pharmacol. 2008 Apr;50(3):376-99. Epub 2008 Jan 26.

### **L-Arginine, L-Isoleucine L-Leucine, L-Lysine, L-Theanine and L-Valine**

Given the limited scientific data available, a formal maximum level for these amino acids has not been established by Health Canada for CEDs. At this time, Health Canada does not have any health and safety concerns with the addition of these amino acids to CEDs at levels up to 300 mg per amino acid per day.

### **3.1.5 Vitamins or Mineral Nutrients not Acceptable for Addition**

#### **Folic acid**

The addition of folic acid to CEDs is not permitted. Folate status data from the Canadian Health Measures Survey indicates that a significant proportion of the population (40-60%) have blood values associated with intakes from all sources above the UL. Note that the UL for folic acid was set due to its potential to mask vitamin B<sub>12</sub>-dependent anemia.

#### **Vitamin A**

The addition of vitamin A (in the form of retinol, retinyl acetate or retinyl palmitate) is not permitted in CEDs. Vitamin A (in the form of retinol, retinyl acetate or retinyl palmitate) is a nutrient with a narrow margin of safety and with serious side effects associated with intakes above the UL (liver toxicity, teratogenicity and increased risk of fracture).

### **3.1.6 Vitamins or Mineral Nutrients not Recommended for Addition**

#### **Nicotinic Acid**

The addition of nicotinic acid to CEDs is not recommended as nicotinic acid is a form of niacin associated with flushing of the skin. However; niacinamide, a form of niacin that has not been associated with flushing of the skin, can be added to CEDs at a level up to 126 mg per day.

## **4.0 Food Additives, Flavours, Herbal Ingredients and Novel Foods as Ingredients in CEDs**

### **4.1 Food Additives**

To be eligible for a TMA, CEDs must not contain non-compliant food additives. The [\*Lists of Permitted Food Additives\*](#) are available on Health Canada's website. The lists are generally organized according to the functional classes of food additives. In this way, they enable the use of additives by specifying the food or foods an additive can be used in, the purpose for addition to that food and the maximum level of use in that food. New products which contain caffeine and meet criteria as outlined in Section 3.0 must be fully compliant with the *Lists of Permitted*

*Food Additives* before a TMAL is issued. Should the *Lists* not allow for a particular use of a food additive, the manufacturer wishing to use that additive is required to file a [food additive submission](#) in accordance with Section B.16.002 of the *Food and Drug Regulations*. Health Canada would subsequently conduct a safety and efficacy evaluation to determine whether the requested food additive use may be added to the *Lists of Permitted Food Additives*.

CEDs are unstandardized beverages within the food regulatory framework. Therefore, they may contain food additives that are permitted in unstandardized beverages, carbonated beverages (if the CED is carbonated), or the broader category of unstandardized foods.

### 4.2 Food Flavours

The Regulations do not require pre-market evaluation of most food flavouring ingredients and there is no “positive” list of permitted flavours in the Regulations. However, the *Food and Drugs Act* prohibits the sale of adulterated foods and section B.01.046 of the *Food and Drug Regulations* lists certain food flavouring substances that would render a food adulterated. These substances are not permitted in any food; including CEDs (refer to Appendix).

Flavouring ingredients used in CEDs and other foods should be of food-grade quality. Flavouring preparations that meet the standards of identity and composition in Division 10 of the *Food and Drug Regulations* are acceptable for use in CEDs. Other flavour ingredients would be considered food-grade if they meet the specifications that are prescribed in the latest edition of the *Food Chemicals Codex* or if they meet the most recent flavouring specifications set by the [Joint FAO/WHO Expert Committee on Food Additives \(JECFA\)](#).

Ultimately, the seller is responsible for ensuring that flavouring substances in their food products do not result in a violation of section 4 of the *Food and Drugs Act*, which prohibits the sale of an unsafe food.

### 4.3 Herbal Ingredients

Herbal ingredients that are acceptable for general use in food are acceptable for use in CEDs. However, Health Canada has identified a number of herbs and botanicals that are considered inappropriate for unrestricted consumption as foods (refer to Appendix) and therefore must not be used in CEDS. However, Health Canada will consider new information that may demonstrate these substances are safe for consumption in foods.

Health Canada’s Food Directorate reviews all the ingredients in the formulations of submitted products. As part of the TMA application, petitioners are required to submit quantitative information for all ingredients used in their product formulation, including herbal and botanical ingredients. Refer to the [TMA submission](#) form for details on the information that is required.

### 4.4 Novel Foods

To be eligible for a TMA, CEDs must not contain unapproved novel ingredients. Division 28 of the *Food and Drug Regulations* requires that all novel foods undergo a mandatory pre-market assessment prior to being authorized for sale in Canada. Novel foods are:

- Products and ingredients that do not have a history of safe use as a food;
- Foods resulting from a process not previously used for food, causing the food to undergo a major change;
- Foods that have been modified by genetic manipulation, also known as genetically modified foods, genetically engineered foods or biotechnology-derived foods.

CEDs that contain an unauthorized novel food ingredient must notify in accordance with Division 28. The nature of the information required as part of a novel food notification can be found in the [Guidelines for the Safety Assessment of Novel Foods](#).

The onus is on the manufacturer or distributor to be in compliance with Division 28, including for ingredients found in CEDs. If you are unsure about the novelty status of particular ingredients, you are encouraged to contact Health Canada at [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca) to further discuss this issue before making a TMA request. If a food is deemed not to be novel, its use defaults to Section 4 of the *Food and Drugs Act* and any other applicable regulations or standards.

More information about novelty determination can be found in the [Guidelines for the Safety Assessment of Novel Foods](#). Refer to section 4.1.1.1 of these guidelines to help determine whether an ingredient is novel or not (history of safe use as a food).

### 5.0 Labelling<sup>3</sup>, Advertising and Claims

In general, all requirements for labelling and advertising for food in the *Food and Drugs Act*, Part B of the *Food and Drug Regulations* and in the *Consumer Packaging and Labelling Act and Regulations* will apply, other than those aspects that are the subject of the TMA. Refer to section 3.0 of the [General Guidance Document for Temporary Marketing Authorization for Foods](#). Further information is available through the Canadian Food Inspection Agency's website regarding [Food Labelling and Advertising](#).

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<sup>3</sup>Please refer to section 5.4 regarding the enhanced labelling requirements for priority allergens, gluten sources and added sulphites.

The following section describes **additional** labelling and advertising requirements **specific** to CEDs. The basis for determining reference amount and serving size is also described, in addition to how certain claims will be assessed.

### 5.1 Advertising

Under the *Food and Drugs Act*, “advertisement” includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of a product. Therefore, all statements, messages and representations, communicated in any medium and designed to promote the consumption or sale of a food are considered to be advertising.

In order to make informed decisions about their health, consumers should always be provided with fair and balanced information about the benefits and the risks associated with CEDs. Notwithstanding the current *Food and Drug Regulations*, since caution statements are required on the labels of CEDs (refer to section 5.3.3); Health Canada recommends that all forms of advertising for CEDs contain the following information (or similar wording):

- The advertised product may not be suitable for everyone;
- Read the label and follow directions for use for the advertised product.

For broadcast advertising, the use of visual disclosures (supers) would be acceptable provided that they are of a size, shade and duration sufficient for an average person to read and comprehend them. In print advertisements, disclosures should be in a type size, location and contrast sufficiently noticeable for an average person to read and comprehend them.

Information that is unacceptable on the label is also unacceptable in advertising. Please refer to sections 5.3.3 (caution statements) and 5.5 (principles governing the acceptability of voluntary statements) for further information.

Because of their high levels of caffeine and other ingredients, CEDs are not recommended for consumption by children. For this reason, these products **must not** be promoted to children. This condition, as well as a condition prohibiting providing samples to children, pregnant or breastfeeding women, is included as part of the Letter of Agreement associated with the TMAL.

### 5.2 Reference Amount, Serving Size and Container Size

The reference amount and serving size refer to quantities of a type of food usually consumed by an individual at one sitting, as determined from consumption data. The quantity is not meant to indicate a recommended or desirable intake. These two parameters provide the basis of compositional criteria for certain nutrition and health claims for foods. Reference amount and

serving size may be subject to change as new consumption data become available, including from the TMA research.

Based on the net quantity of CEDs that is typically sold per container for single serving consumption, the reference amount for CEDs has been established at 500 mL. This amount will be used for the purposes of the TMA.

In accordance with B.01.002A of the *Food and Drug Regulations*, a serving of stated size of a CED shall be based on the food as offered for sale and expressed in millilitres. Where the container of the product contains 150% or less of the reference amount, a serving of stated size shall be the net quantity of the food in the container (refer to B.01.002A(2)(c) of the *Food and Drug Regulations*). Note that a CED that cannot be re-sealed is considered a single-serving container, regardless of container size.

Re-sealable containers for CEDs above 750 mL are considered multi-serving containers<sup>4</sup> for which the serving size (500 mL) will be the same as the reference amount.

All declarations of content made on the label of a CED container must be made based on the same serving of stated size.

### 5.3 Required Statements

#### 5.3.1 Quantitative Declaration of Caffeine Content

All CEDs are required to display quantitative declaration of caffeine content on product labels. Caffeine content includes all sources of caffeine in the product. In addition to synthetic caffeine, natural caffeine sources, such as guarana and yerba mate, must be included in determining the caffeine content. For single-serving containers, caffeine content must be declared on a per container basis whether or not the container is re-sealable. Refer to section 5.2 above for guidance regarding when a container is considered to be a single-serving container.

For multi-serving containers, caffeine content must be declared on a per serving basis of 500 mL.

#### 5.3.2 Qualitative Declaration of Caffeine

All CEDs are required to display the following statement on product labels:

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<sup>4</sup> A tolerance of 15 mL is considered in determining multi-serving containers in accordance with *Consumer Packaging and Labelling Regulations*, Section 38. This means that CED re-sealable containers with net contents within the tolerance limit of 750 mL (between 751 and 764 mL) may be considered a single-serving container.

- “High caffeine content”.

It is recommended that a consistent statement be used in describing the caffeine content. However, no objection will be taken if synonyms equivalent in meaning to the above statement are used (for example, “high in caffeine”).

### 5.3.3 Caution Statements

The following caution statements should be grouped together, without any intervening material, preferably under a standardized bolded heading “Caution/Mise en garde” or “Caution/Attention”. A distinct heading that stands out from other information on a label makes the information more noticeable by consumers. Alternatively, these statements may be presented in bold text:

- “Do not consume more than (X) container(s)/serving(s) daily” or “Usage: (X) container(s)/serving(s) maximum daily”;
- “Not recommended for children, pregnant or breastfeeding women and individuals sensitive to caffeine”;
- “Do not mix with alcohol”.

The maximum number of containers or servings must not result in the daily maximum limit being exceeded for any added vitamins, minerals or amino acids set out in section 3.1.2.

### 5.3.4 Product Identification

It is recommended that a consistent statement be used to identify products. The statement “caffeinated energy drink” must appear on the principal display panel of the label when it is not clear from the brand name that the product is in fact a CED.

Water is a standardized beverage; therefore, the common name “water” may not be used in the brand name to describe a CED as these products do not meet the provisions set in the standard for water (refer to section B.12.001 of the *Food and Drug Regulations*). However, the term “water beverage” or similar wording may be used in the brand name of a CED. Please note that the statement “caffeinated energy drink” must also appear on the principal display panel for these “water beverage” products.

### 5.3.5 Quantitative Declaration of Ingredients Other than Caffeine

NHP ingredients, such as herbal ingredients and their isolates, have pharmacological effects when consumed at therapeutic levels. Although many of these ingredients have been deemed

safe for use in NHPs, their use in food presents a different context. Foods are typically consumed ad libitum, daily and over a lifetime, while the consumption of NHPs is limited by specific label instructions outlining the conditions of use including the daily dose, directions for use and duration of use. As a condition of the TMA, CEDs have similar conditions of use as NHPs; however, until results of the TMA research can determine whether these conditions of use are being followed, additional precautions may be required to mitigate risk.

Due to the potential health implications of selected bioactive ingredients, consumers need to be alerted to their presence as well as to their levels in food products. This can help them adjust their intake of individual ingredients from multiple sources and assist them, along with their health care providers, to assess the potential for contraindications or interactions with medications. This is consistent with the approach and accompanying rationale for the declaration of caffeine levels.

When added to CEDs, the quantity of select bioactive ingredients (in other words, those ingredients that meet the criteria indicated below) per serving of stated size must be declared if the ingredient does not have an accepted food purpose and meets one of the following conditions:

- A limit of addition is specified for the ingredient by Health Canada (refer to table in section 3.1.2, for example, taurine); or
- A dosage is established in the [monographs](#) of the Natural Health Product Directorate (NHPD) or another recognized source, such as Expanded Commission E monographs, and when an individual consumes the product while respecting the maximum number of containers or servings in the caution statement on the product label, s/he will reach the dosage in the monograph or the recognized source. Note that the inclusion of certain ingredients may trigger the need for additional labelling (for example, caution statements). This determination will be made on an ingredient-by-ingredient basis and will take into account dosage.

TMA applicants are advised to consult with Health Canada if they have questions as to whether the level of an ingredient of interest should be declared (refer to contact information in section 1.2.1).

The ingredients listed below have accepted food purposes and are excluded from the above requirement:

- A vitamin, mineral nutrient;
- A food additive;
- A flavouring agent;

- Other food ingredients with a food purpose that provide Calories and/or hydration.

Note that a quantitative declaration of an amino acid outside the ingredient listing can be made only for a product that is a source of protein or that meets specified exemptions described in B.01.305(2) of the *Food and Drug Regulations*. Petitioners are advised to consult Health Canada regarding making quantitative declaration of amino acids in the ingredient listing.

### 5.3.6 Other Required Information

The company name and identity of the principal place of business must be provided on the product label. Companies are encouraged to provide a toll-free number on the label to facilitate the reporting of consumption incidents by the public (refer to section 2.2).

### 5.3.7 Placement of Required Statements

Quantitative declarations of caffeine (refer to section 5.3.1) and other ingredients (refer to section 5.3.5) should be placed immediately below the Nutrition Facts table or adjacent to the ingredient listing. The same serving size must be used as in the Nutrition Facts table.

Qualitative caffeine declaration (refer to section 5.3.2) should be adjacent to the quantitative declaration or the caution statements, unless the qualitative declaration appears on the principal display panel.

Caution statements (refer to section 5.3.3) should be in close proximity to the Nutrition Facts table, either below or adjacent to it.

For example of how required statements may be displayed on product labels refer to section 5.6 Sample Label.

### 5.3.8 Legibility and Prominence of Required Statements

Required statements specific to CEDs are of similar public health significance as the information provided in the Nutrition Facts table. Therefore, some of the same requirements for legibility and prominence should be met. This means that the required statements for CEDs should be displayed in letters of the same size, using upper and lower case letters, contrast (for example, black text on white background) and prominence, similar to that required for the core information in the Nutrition Facts table.

### 5.4 Priority Allergens, Gluten Sources, and Sulphites

CEDs must also meet the labelling regulations set out in Sections B.01.010.1 to B.01.010.3 of the *Food and Drug Regulations*. Some CEDs may contain certain ingredients such as whey protein, cream, soy, or caramel colour, which could trigger allergen, gluten, or sulphite labelling requirements in a prescribed manner. CED products must comply with all food labelling requirements to be eligible for a TMA including these enhanced labelling requirements.

Food manufacturers are also urged to comply with Health Canada's policy on [\*the use of food allergen precautionary statements on prepackaged foods\*](#) which was developed for those consumers who may need to be warned about the potential inadvertent presence of allergens, gluten source or sulphites through cross-contamination.

Note that should Health Canada identify a significant health risk with respect to the undeclared presence of priority food allergens, added sulphites or gluten sources in a prepackaged CED, the Canadian Food Inspection Agency will take appropriate enforcement action, which may include product recall.

### 5.5 Voluntary Statements

As noted in section 3.2 of the [\*General Guidance Document for Temporary Marketing Authorization for Foods\*](#), certain statements, such as nutrient content claims and health claims may be made on the label or in advertisements for food products on a voluntary basis. However, when they are made, they must comply with the *Food and Drugs Act* and the food provisions of the *Food and Drug Regulations* and applicable guidance. Note also that when any statement about an ingredient is made on the label, other than as part of the ingredient listing, the level of the ingredient in the food should be declared in grams or milligrams per serving of stated size. Such claims are considered implied health claims. As such, the levels in a serving of the food should be biologically meaningful, supported by scientific evidence and documented in accordance with [\*guidance for preparing health claim submissions\*](#). Depending on the ingredient, quantitative declaration may be required as per section 5.3.5.

Companies marketing CEDs in Canada should be aware that nutrient content claims and health claims on food products must be linked to specific substance(s) in the product.

Health claims for food in general should be expressed in specific terms rather than general terms, such that claimed effects are both measurable and quantifiable, and therefore allow scientific verification. This will reduce the possibility of claims being vague, uninformative or misleading. For example, a claim about “temporarily restoring alertness” is more specific than a claim about “enhancing cognitive performance”.

Listed below are several principles by which the acceptability of certain claims on CEDs will be assessed.

### 5.5.1 Claims Related to Physical Performance

The use of CEDs for sport performance is not supported by a recently conducted evidence-based review<sup>5</sup>. Caffeine's potential ergogenic effects are likely related to its role as a central nervous system stimulant and the associated decreased perception of physical effort it imparts to its users<sup>6</sup>. The consumption of CEDs within the context of sport performance is not recommended as their intake could lead to serious adverse effects, especially when used for purposes of hydration. New and novice users who have had limited exposure to caffeine should be careful as adverse effects of caffeine may be more pronounced<sup>5,6</sup>. Health Canada's advice on the consumption of CEDs for sport performance is consistent with this assessment.

In this context, health claims made on these products should not contradict this advice nor should the claims be likely to convey mixed messages about the use of CEDs. This directive applies in particular to any health claims (implied or explicit) making reference to physical performance (for example, physical exertion, endurance, aerobic, anaerobic, power, strength, motor performance, recovery, or sports). Modifications to the claim wording and/or conditions of use (for example, amount, timing and the targeted group for use of the product) may be necessary to allow for the safe use of CEDs. For example, the addition of another message that would help to decrease the likelihood that CEDs are perceived as sports drinks or for rehydration purposes could be acceptable, such as "not intended for re-hydration". The effectiveness of the modified claim statement in mitigating the health concern will be assessed through research required to be conducted as part of the TMA.

Petitioners are encouraged to consult with Health Canada to discuss any proposed claims related to physical performance to ensure these claims do not contradict Health Canada's advice (refer to contact information in section 1.2.1).

### 5.5.2 Claims Related to General or Specific Health Benefits

Unlike most foods and beverages, the use of the term "energy", as part of a CED's product name or health claim does not refer to Calories. In this case, the use of the term "energy" is considered an implied health claim consistent with the primary purpose for which this product category has been represented (for example, to provide mental stimulation for a short period of time). Claims that refer to the product as a source of essential nutrients such as vitamins and mineral nutrients,

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<sup>5</sup> Position of the American Dietetic Association, Dietitians of Canada and the American College of Sports Medicine: Nutrition and athletic performance. *J Am Diet Assoc* 2009; 109(3):509-27.

<sup>6</sup> Higgins JP, Tuttle TD, Higgins CL. Energy beverages: Content and safety. *Mayo Clin Proc* 2010; 85(11):1033-41.

as well as claims referring to the maintenance of good health or normal growth and development for known nutrients, create an impression that the product can be consumed long-term as part of a daily eating pattern. These claims are not appropriate for products required to carry caution statements that specify daily consumption limits, or that the product is not suitable for the general population. Claims must not create an impression that the product can be consumed as part of a daily eating pattern. In addition, claims must not promote consumption by children or inappropriate use.

### 5.5.3 Calorie-Free and Sugar-Free Claims

The reference amount of 500 mL would disqualify some products in single serving containers less than 500 mL from making Calorie-free and sugar-free claims (refer to table following B.01.513 of the *Food and Drug Regulations*). An exemption from this section of the *Food and Drug Regulations* with respect to the reference amount requirement will be allowed for these claims for the duration of the TMA. Health Canada will further examine this section of the *Food and Drug Regulations* to support a permanent solution in the future.

### 5.5.4 Placement and Prominence of Voluntary Statements

To ensure that voluntary claims do not detract consumers' attention from the caution statements, it is recommended that voluntary claims not be more prominent than the required caution statements. If a voluntary claim is made on the principal display panel, it is recommended that a statement to the effect "See caution statements below (or adjacent to) the Nutrition Facts table" in the same type size and prominence should appear on the upper right corner of the same panel.

## 5.6 Sample Label

To illustrate how the required statements may be displayed on product labels, two sample labels are provided (refer to figure 1).

The following resources administered by the Canadian Food Inspection Agency provide additional information that will assist TMA applicants in meeting food labelling requirements:

- Compendium of Templates for Nutrition Facts Tables;
  - This was created in QuarkXPress 4.1 and is available upon request from your [local Canadian Food Inspection Agency office](#) ;
- [Food Labelling and Advertising](#);
- [Nutrition Labelling Toolkit](#).

**Figure 1:** Two examples are provided here for illustrative purposes only to show how the required statements for CEDs may be displayed on product labels.

**Example A:** The Nutrition Facts table does not reflect the style and format specified in the *Food and Drug Regulations* respecting Nutrition Labelling. Refer to the Canadian Food Inspection Agency guide [Food Labelling and Advertising](#) for more information regarding specifications for the Nutrition Facts table.

473 mL

**BRAND@/MD**

**ENERGY DRINK**

**BOISSON ÉNERGISANTE**

Nutrition Facts	
Valeur nutritive	
Per can (473 mL) / par canette (473 mL)	
Amount	% Daily Value
Teneur	
Calories / Calories	260
Fat / Lipides	0 g 0 %
Sodium / Sodium	140 mg 6 %
Carbohydrate / Glucides	62 g 21 %
Sugars / Sucres	62 g
Protein / Protéines	2 g
Riboflavin / Riboflavine	200 %
Niacin / Niacine	200 %
Vitamin B <sub>6</sub> / Vitamine B <sub>6</sub>	200 %

Not a significant source of saturated fat, trans fat, cholesterol, fibre, vitamin A, vitamin C, calcium or iron.

Source négligeable de lipides saturés, lipides trans, cholestérol, fibres, vitamine A, vitamine C, calcium et fer.

**High caffeine content**  
**Caution:** Do not consume more than 2 cans daily. Not recommended for children, pregnant or breastfeeding women and individuals sensitive to caffeine. Do not mix with alcohol.

**Teneur élevée en caféine**  
**Mise en garde :** Ne pas consommer plus de 2 canettes par jour. N'est pas recommandé pour les enfants, les femmes enceintes ou qui allaitent et les personnes sensibles à la caféine. Ne pas mélanger avec de l'alcool.

**Contains (per can): Caffeine 160 mg, Taurine 2000 mg, XXX x mg, XXX x mg, XXX x mg.**  
**Contient (par canette): Caféine 160 mg, Taurine 2000 mg, XXX x mg, XXX x mg, XXX x mg.**

**Ingredients: Carbonated water, Sucrose, Glucose-Fructose, Guarana seed extract, Taurine, Corn maltodextrin, Glucuronolactone, Caffeine, Panax ginseng root extract, Ginkgo biloba leaf extract, Niacinamide, Riboflavin, Pyridoxine hydrochloride, Citric acid, Sodium benzoate, Natural flavour, Colour.**

**Ingrédients: Eau gazeifiée, saccharose, glucose-fructose, extrait de graines de guarana, taurine, maltodextrine de maïs, glucuronolactone, caféine, extrait de racine de Panax ginseng, extrait de feuilles de Ginkgo biloba, niacinamide, riboflavine, chlorhydrate de pyridoxine, acide citrique, benzoate de sodium, arôme naturel, colorant.**

**ABC Company, Toronto, Canada M1X 1Y1**

**Example B:** The Nutrition Facts table does not reflect the style and format specified in the *Food and Drug Regulations* respecting Nutrition Labelling. Refer to the Canadian Food Inspection Agency guide [Food Labelling and Advertising](#) for more information regarding specifications for the Nutrition Facts table.

<p>473 mL</p>	<p><b>BRAND®/MD</b></p> <p><b>ENERGY DRINK</b></p> <p><b>BOISSON ÉNERGISANTE</b></p>	<p><b>Nutrition Facts</b> <b>Valeur nutritive</b></p> <p>Per can (473 mL) / par canette (473 mL)</p> <table border="1"> <thead> <tr> <th>Amount Teneur</th> <th>% Daily Value % valeur quotidienne</th> </tr> </thead> <tbody> <tr> <td><b>Calories / Calories</b> 260</td> <td></td> </tr> <tr> <td><b>Fat / Lipides</b> 0 g</td> <td><b>0 %</b></td> </tr> <tr> <td><b>Sodium / Sodium</b> 140 mg</td> <td><b>6 %</b></td> </tr> <tr> <td><b>Carbohydrate / Glucides</b> 62 g</td> <td><b>21 %</b></td> </tr> <tr> <td>Sugars / Sucres 62 g</td> <td></td> </tr> <tr> <td><b>Protein / Protéines</b> 2g</td> <td></td> </tr> <tr> <td>Riboflavin / Riboflavine</td> <td><b>200 %</b></td> </tr> <tr> <td>Niacin / Niacine</td> <td><b>200 %</b></td> </tr> <tr> <td>Vitamin B<sub>6</sub> / Vitamine B<sub>6</sub></td> <td><b>200 %</b></td> </tr> </tbody> </table> <p><small>Not a significant source of saturated fat, trans fat, cholesterol, fibre, vitamin A, vitamin C, calcium or iron.</small></p> <p><small>Source négligeable de lipides saturés, lipides trans, cholestérol, fibres, vitamine A, vitamine C, calcium et fer.</small></p> <p><b>High caffeine content</b>                  Contains (per can): Caffeine 160 mg, Taurine 2000 mg, XXX x mg, XXX x mg, XXX x mg.  <b>Teneur élevée en caféine</b>                  Contient (par canette): Caféine 160 mg, Taurine 2000 mg, XXX x mg, XXX x mg, XXX x mg.</p> <p><b>Usage: 2 cans maximum daily. Not recommended for children, pregnant or breastfeeding women, individuals sensitive to caffeine or to be mixed with alcohol.</b>                  Consommation : maximum 2 canettes par jour. N'est pas recommandé pour les enfants, les femmes enceintes ou qui allaitent, les personnes sensibles à la caféine ou en combinaison avec de l'alcool.</p>	Amount Teneur	% Daily Value % valeur quotidienne	<b>Calories / Calories</b> 260		<b>Fat / Lipides</b> 0 g	<b>0 %</b>	<b>Sodium / Sodium</b> 140 mg	<b>6 %</b>	<b>Carbohydrate / Glucides</b> 62 g	<b>21 %</b>	Sugars / Sucres 62 g		<b>Protein / Protéines</b> 2g		Riboflavin / Riboflavine	<b>200 %</b>	Niacin / Niacine	<b>200 %</b>	Vitamin B <sub>6</sub> / Vitamine B <sub>6</sub>	<b>200 %</b>	<p><b>Ingredients:</b> Carbonated water, Sucrose, Glucose-Fructose, Guarana seed extract, Taurine, Corn maltodextrin, Glucuronolactone, Caffeine, Panax ginseng root extract, Ginkgo biloba leaf extract, Niacinamide, Riboflavin, Pyridoxine hydrochloride, Citric acid, Sodium benzoate, Natural Flavour, Colour.</p> <p><b>Ingédients:</b> Eau gazéifiée, saccharose, glucose-fructose, extrait de graines de guarana, taurine, maltodextrine de maïs, glucuronolactone, caféine, extrait de racine de Panax ginseng, extrait de feuilles de Ginkgo biloba, niacinamide, riboflavine, chlorhydrate de pyridoxine, acide citrique, benzoate de sodium, arôme naturel, colorant.</p> <p>ABC Company Toronto, Canada MX 1Y1</p>
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### Appendix: Reference List of Ingredients

#### Negative List of Ingredients

The ingredients found on the Negative List are divided into three categories: flavouring ingredients that are not permitted in any foods (including CEDs); herbal ingredients that are considered to be inappropriate for unrestricted consumption in foods; and other ingredients that are not permitted in CEDs. These lists of ingredients are not exhaustive and may be revised as new information becomes available.

#### Prohibited Flavouring Substances (Section B.01.046, Division 1 of Part B of the *Food and Drug Regulations*):

- Coumarin, an extract of tonka beans, the seed of *Dipteryx odorata* Willd. or *Dipteryx oppositifolia* Willd.
- Dihydrosafrole
- Isosafrole
- Oil of American sassafras from *Sassafras albidum* (Nutt.) Nees
- Oil of Brazilian sassafras from *Ocotea cymbarum* H.B.K.
- Oil of camphor sassafrassy from *Cinnamomum camphorum* Sieb
- Oil of micranthum from *Cinnamomum micranthum* Hayata
- Safrole
- Oil, extract or root of calamus from *Acorus calamus* L.
- Cinnamyl anthranilate

#### Herbs and Botanicals Previously Identified as Inappropriate for Unrestricted Consumption as Foods:

- Cascara sagrada
- Chaparral
- Ephedra

- Germander
- Gotu kola
- Horsetail
- Kava-kava
- Khat
- Senna
- Acorus calamus (which is prohibited under B.01.046)
- Arnica (Arnica montana, wolf's bane, leopard's bane)
- Comfrey
- Magnolia officinalis
- Pleurisy root (Asclepias tuberosa)
- Stephania tetrandia
- Yellow jessamine (Gelsemium sempervirens)

**Other Ingredients Not Permitted in CEDs (refer to explanation in section 3.1.5):**

- Folic acid
- Vitamin A (in the form of retinol, retinyl acetate or retinyl palmitate)