



# Dirección Nacional de Medicamentos

República de El Salvador, América Central

## UNIDAD DE INSPECCIÓN Y FISCALIZACIÓN



### COMUNICACIÓN DE ALERTA

Santa Tecla, 28 de Julio de 2016

#### LA DIRECCIÓN NACIONAL DE MEDICAMENTOS (DNM) ALERTA SOBRE *PRODUCTO: DR's SECRET BIO HERBS COFFEE Y EXHILARATE*

Nivel de alerta: 1

Nombre del producto: DR's Secret Bio Herbs Coffee y Exhilarate

Presentación/Forma Farmacéutica: Cápsulas y Tabletas

Número de registro sanitario: No posee

Laboratorio Fabricante: No se detalla

Lotes: No se detalla

Fecha de vencimiento: No se detalla

Entidad emisora de la Alerta: Health Canadá

País de Origen: Canadá

Fecha de emisión de la Alerta: 28 de Julio de 2016

Descripción del problema encontrado: Health Canadá informa que por medio de la FDA se ha identificado contenido no declarado de tadalafil, y sibutramina + desmetilsibutramina + fenoltaleína en los productos antes mencionados. De acuerdo a la investigación realizada por la DNM No se encontró registro sanitario alguno ni importaciones de los productos.

La DNM alerta a toda la población a abstenerse de adquirir y/o suministrar éstos productos, en virtud de que su uso representa un riesgo para la salud de la persona que lo consuma. En razón de que los productos DR's Secret Bio Herbs Coffee y Exhilarate NO cumplen con los requerimientos de calidad que avale su seguridad, calidad y eficacia.

La DNM recomienda no adquirir este tipo de productos ya que puede generar un riesgo a la salud. Así mismo recuerda adquirir los medicamentos en lugares autorizados por la DNM. Cualquier duda puede recurrir a ésta Dirección llamando al teléfono gratuito 136.

Se informa que la DNM continuará las acciones de vigilancia, como el aseguramiento de productos, para evitar la venta de los mismos porque representan un riesgo a la población.

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### ANEXOS



#### Recalls and safety alerts

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#### Foreign Product Alert: DR's Secret Bio Herbs Coffee, Exhilarate, Ultimate Nutrition Amino Gold (1000mg capsules, 1000mg tablets, 1500mg tablets), Michael's® Naturopathic Programs Cholesterol Metabolism Factors

Report a Concern

**Starting date:** July 28, 2016  
**Posting date:** July 28, 2016  
**Type of communication:** Foreign Product Alert (FPA)  
**Subcategory:** Natural health products  
**Source of recall:** Health Canada  
**Issue:** Important Safety Information, Undeclared Substance  
**Audience:** General Public  
**Identification number:** RA-59588

- [Issue](#)
- [What you should do](#)
- [Background](#)
- [Report health or safety concerns](#)
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#### Issue

These foreign health products have been found by regulators in other countries to contain undeclared allergens and or undeclared drug ingredients.

The products are not authorized for sale in Canada and have not been found in the Canadian marketplace but it is possible they may have been brought into the country by travellers or purchased over the Internet.

#### Unauthorized Health Products

| Product Name(s)                          | Hazard(s) Identified | Source of Alert | Other product information, if available | Images |
|------------------------------------------|----------------------|-----------------|-----------------------------------------|--------|
| Unauthorized Sexual Enhancement Products |                      |                 |                                         |        |

<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/59588a-eng.php#images-images>

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| Product Name(s)                                | Hazard(s) Identified                                          | Source of Alert                            | Other product information, if available | Images |
|------------------------------------------------|---------------------------------------------------------------|--------------------------------------------|-----------------------------------------|--------|
| DR's Secret Bio Herbs Coffee                   | Undeclared tadalafil                                          | United States Food and Drug Administration |                                         |        |
| <b>Unauthorized Weight Loss Products</b>       |                                                               |                                            |                                         |        |
| Exhilarate                                     | Undeclared sibutramine, desmethylsibutramine, phenolphthalein | United States Food and Drug Administration |                                         |        |
| <b>Unauthorized Dietary Supplements</b>        |                                                               |                                            |                                         |        |
| Ultimate Nutrition Amino Gold Capsules 1000mg  | Undeclared milk                                               | United States Food and Drug Administration |                                         |        |
| Ultimate Nutrition Amino Gold Tablets (1000mg) | Undeclared milk                                               | United States Food and Drug Administration |                                         |        |
| Ultimate Nutrition Amino Gold Tablets (1500mg) | Undeclared milk                                               | United States Food and Drug Administration |                                         |        |



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| Product Name(s)                                                    | Hazard(s) Identified    | Source of Alert                            | Other product information, if available                                                                                                                                                                                                                                                                                                                                              | Images |
|--------------------------------------------------------------------|-------------------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| Michael's® Naturopathic Programs<br>Cholesterol Metabolism Factors | Undeclared milk and soy | United States Food and Drug Administration | 90 count, 180 count, 270 count<br><br>Lot # (best by date): <ul style="list-style-type: none"><li>■ 1307013 (6/2016)</li><li>■ 1310060 (10/2016)</li><li>■ 1402177 (3/2017)</li><li>■ 1405356 (6/2017)</li><li>■ 1408114 (8/2017)</li><li>■ 1410186 (11/2017)</li><li>■ 1501476 (2/2018)</li><li>■ 1505367 (6/2018)</li><li>■ 1510296 (11/2018)</li><li>■ 1602062 (3/2019)</li></ul> |        |

### What you should do

- Contact Health Canada at 1-800-267-9675 or by completing an [online complaint form](#) if you find a product listed above in the Canadian marketplace.
- Consult with a healthcare professional if you have health concerns related to the use of any of these products.
- Read the label of the products you buy to verify that they have been assessed by Health Canada for safety, effectiveness and quality. Health products that have been authorized for sale by Health Canada will have an eight-digit Drug Identification Number (DIN), Natural Product Number (NPN) or a Homeopathic Drug Number (DIN-HM).

### Background

Prescription drugs should **only** be used under the supervision of a healthcare professional.

<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/59588a-eng.php#images-images>

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- Recalls and safety alerts

**Desmethyisibutramine** is an unauthorized substance similar to sibutramine, a prescription drug previously used to treat obesity and may pose similar health risks. Sibutramine is no longer authorized for sale in Canada because of its association with an increased risk of cardiovascular side effects such as heart attack and stroke. Other side effects include increased blood pressure and heart rate, dry mouth, difficulty sleeping and constipation.

**Milk** can cause allergic reactions in certain individuals. An allergic reaction occurs when the body's immune system reacts to a foreign substance. The reaction can range from mild to life-threatening (i.e. an anaphylactic reaction). A mild reaction includes itchy and/or runny eyes and nose, skin rash and sneezing. A severe reaction includes swelling, difficulty breathing and/or swallowing, dizziness, a sudden drop in blood pressure and loss of consciousness.

**Phenolphthalein** was previously used as a laxative but is no longer authorized for sale in Canada because it may cause cancer. Additional side effects include decreased blood pressure, skin rash and gastrointestinal bleeding.

**Sibutramine** was previously used to treat obesity but is no longer authorized for sale in Canada because of its association with an increased risk of cardiovascular side effects such as heart attack and stroke. Other side effects include increased blood pressure and heart rate, dry mouth, difficulty sleeping and constipation.

**Soy** can cause allergic reactions in certain individuals. An allergic reaction occurs when the body's immune system reacts to a foreign substance. The reaction can range from mild to life-threatening (i.e. an anaphylactic reaction). A mild reaction includes itchy and/or runny eyes and nose, skin rash and sneezing. A severe reaction includes swelling, difficulty breathing and/or swallowing, dizziness, a sudden drop in blood pressure and loss of consciousness.

**Tadalafil** is a prescription drug used to treat erectile dysfunction. It should only be taken under the supervision of a healthcare professional. Tadalafil should not be used by individuals taking any kind of nitrate drug (e.g., nitroglycerine) as it can cause potentially life-threatening low blood pressure. Individuals with heart problems are at increased risk of cardiovascular side effects such as heart attack, stroke, chest pain, high blood pressure and abnormal heartbeat. Other side effects include headache, facial flushing, indigestion, dizziness, abnormal vision, and hearing loss.

#### Report health or safety concerns

To report a side effect to a health product to Health Canada:

- Call toll-free at 1-866-234-2345
- Visit Health Canada's Web page on [Adverse Reaction Reporting](#) for information on how to report online, by mail or by fax

As of July 27, 2016, no adverse reactions suspected to be associated with the use of these products have been reported to Health Canada.

#### Images

Select thumbnail to enlarge



<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/59698e-eng.php#images-images>

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- Recalls and safety alerts

### For more information

- [Adulteration of natural health products](#)
- [Buying drugs over the Internet](#)
- [The safe use of health products for weight loss](#)
- [Risks of buying natural health products online](#)

Date modified: 2016-07-28

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