



# The SFDA General Rules for Products claim

Date of publication	2021/09/21
---------------------	------------



# **The SFDA General Rules for Products Claim**

Saudi Food & Drug Authority

Kingdom of Saudi Arabia



## **Saudi Food & Drug Authority**

### **Vision and Mission**

#### **Vision**

To be a leading international science-based regulator to protect and promote public health.

#### **Mission**

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed



### Document Control

Version	Author	Date	Comments
1	Products Classification Department	2021/09/21	First edition



## **Table of Contents**

<b>1. Introduction</b>	6
<b>1.1 Objectives</b>	6
<b>1.2 Scope</b>	6
<b>1.3 Definitions</b>	6
<b>2. General Principles and Specific Rules for Claims</b>	8
<b>2.1 General principles</b>	8
<b>2.2 Specific Rules for Claims</b>	9
<b>2.2.1 Health and Nutrition Claims on Food Products</b>	9
<b>2.2.2 Drug and Herbal claims</b>	9
<b>2.2.3 Health Product Claims</b>	11
<b>2.2.4 Cosmetics Claims</b>	12
<b>2.2.5 Medical Devices Claims</b>	12
<b>Appendix</b>	13
<b>Appendix A</b>	13
<b>Appendix B</b>	16
<b>References</b>	17



## 1. Introduction

The Product classification procedure depends on several factors such as; primary mode of action, intended use, ingredients, claims, etc. Claims are an important element of this process, which are presented on the labels of the products or in any marketing documents and materials from the manufacturers. Sometimes, the claims can influence the classification decision of the product. For example, a hand soap that claims to only wash hands is considered to be a cosmetic product; however, a hand soap that claims to kill viruses and disinfect the hands is not a cosmetic product, even if the ingredients are cosmetic. Therefore, it is essential to provide this guidance as a clarification for these claims.

### 1.1 Objectives

The guidance presents general rules of claims made on products subject to the Saudi food and drug authority (SFDA) regulation. Additionally, the guidance presents examples for accepted, unaccepted claims and claims that are not considered to be under the responsibility of the SFDA. It also shows general principles of claims that are labeled on products. It is important to note that this guidance is only to help applicants to determine what kind of claims they can label on their product(s).

### 1.2 Scope

This guidance pertains claims that are under the responsibility of different sectors regulated within the SFDA according to Saudi Food and Drug Authority Law Royal Decree No. (M/6) Dated 25/1/1428AH

### 1.3 Definitions

**1.3.1 Claim:** Any message or representation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a product has particular characteristics.

**1.3.2 Health claim (on Food Products):** any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

**1.3.3 Nutrient:** means any substance normally consumed as a constituent of food:

- 1 which provides energy.
- 2 which is needed for growth, development and maintenance of life.
- 3 a deficit of which will cause characteristic bio-chemical or physiological changes to occur in the body.

**1.3.4 Foodstuff:** any substance, raw, fresh, processed, unprocessed, or partially processed, intended for human consumption, including any component introduced into the product during the processing, preparation or treatment of food.



**1.3.5 Drug:** A) An article intended for use in the diagnosis, cure mitigation, treatment, or prevention of disease and which is intended to affect the structure or function of the body

B) Any Pharmaceutical Product manufactured in a pharmaceutical dosage form and contain one or more of active substance used externally or internally in treatment of a disease in human or animal, or prevent the disease.

**1.3.6 Herbal Product:** A) Any plant or herb in pharmaceutical dosage form that is used to treat or prevent diseases

B) Any finished labeled medicinal products that contain as active ingredients aerial or underground parts of plants or other plant materials or the combination of them, whether in crude state or plant preparation that is used to treat or prevent diseases or ailments or to promote health and healing. Plant materials include juices, gums, fatty oils and any other substance of this nature.

**1.3.7 Health Product:** Finished labeled products in pharmaceutical dosage forms, which are usually low risk ingredients that intended to restore, correct, modify physiological functions by exerting pharmacological, immunological or metabolic actions

**1.3.8 Cosmetic:** Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.

**1.3.9 Medical Device:** any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,
- Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;
- Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

## **2. General Principles and Specific Rules for Claims:**

Claims submitted to the SFDA should follow a strict set of general principles and specific rules based on the product sought to be claimed. The general principles of claims have the potential to add substances to the role to define what is acceptable and what is not, whereas the framework can be robust, through the use of general principles and specific rules for claims.

### **2.1 General Principles:**

There are general rules regarding claims, and there are specific rules that depends on the class of the product, These general rules doesnot reflect the claim assessment in the scientific sectors. Where it only consider as a general guidance in classification assessment. And those are as follow:

#### **1. Truthfulness**

Claims should state the truth about the product. There should be no overstatement, ambiguity, or deception.

#### **2. Evidential support**

All claims should be supported by evidence relevant to the claims, which should come from trustworthy resources. This includes references such as scientific organizations, historic use, regulatory authorities, SFDA regulation related to (Food, Drug and medical device), etc... The evidence of the product might be based on its ingredients or the overall finished product, if the applicant is able to provide the evidence when asked.

#### **3. Use of Scientific Data:**

- Scientific data that cannot be validated by the general public should not be used in the claims.
- Research results or unnecessary quotations from scientific publications should not be used if are used to overstate the value of the product.
- Terms such as “proven by clinical trials” or “clinically proven” for health supplements should be avoided, as it implies effects on treatment of medical conditions or passing standards applicable for medicines and drugs or pharmaceuticals.

#### **4. Language:**

Claims should be written in either Arabic And English. Moreover, claims should not be confusing, and in alliance with SFDA rules and regulation of required labeling information.





## **2.2 Specific Rules for Claims:**

In the below the specific claims that divided by sectors and departments. Each product is required certain requirement for there claims.

### **2.2.1 Health and Nutrion Calims on Food Products:**

Below is a list of claims that are not allowed in foods:

1. Claims that refer to specific percentage or amount of weight loss.
2. Claims that refer to recommendations by individual doctors or health professionals.
3. Claims that suggest health could can affected by not consuming the food.
4. Claims refers to food, which can be used in preventing, mitigating, treating, or curing a disease, disorder, or a particular physiological condition.
5. Claims stating that food will provide all the adequate amounts of all essential nutrients.
6. Claims implying that a regular or balanced diet foods cannot supply adequate amounts of nutrients
7. Claims, which cannot be proven by scientific evidence.
8. Claims that may rise doubts about safety of food products or can exploit fear to consumers.
9. Meaningless claims, including incomplete comparatives and superlatives.
10. Claims which consist of meanings such as good hygienic practice, wholesomeness, and healthy,
11. Claims made on food intended exclusively for infants and children.

Note: Please refer to Guideline for Submitting a claim Evaluation Request of Health and Nutrition Claims

Note: If the claim is not in the approved Health claims mentioned in the above Technical Regaulation (SFDA.FD 2333), it can be submitted to be evaluated according to guildlines published in SFDA website

### **2.2.2 Drug and Herbal Claims:**

If the product is presented with a high-risk claim such as treating or preventing diseases, this means that the product will be subject under either, drug, or herbal jurisdictions

#### **Claim to Treat or Prevent Diseases**

Claims made explicitly or implicitly to “protect, prevent, relieve symptoms, cure, heal, eliminate, etc.” can be regarded as medical claims.



For example:

- Direct claims to treat or prevent medical condition
- Graphics that imply medical use
- Use of promotional material stating or implying the use to treat or prevent disease
- Reference to effect on pharmacological, immunological, or metabolic function

Note: In Appendix A some examples for Herbs and Medicinal Plants.

Note: Claims cannot arouse fear or abuse the superstition of the public.

Note: Please refer to SFDA's List of registered herbal drugs.

Note: Deciding whether a claim is medical or not, is not always straightforward. There are three levels of claims that describe their risks:

**High Risks:**

- Treats, cures, manages any disease, disorder, or condition.
- Prevention of any disease, disorder, or condition.
- Treatment of specific vitamin or mineral deficiency diseases.

**Medium Risks:**

- Health enhancement.
- Reduction of risk of a disease, disorder, or condition.
- Reduction in frequency of a discrete event.
- Aids / assists in the management of a named symptom / disease / disorder / condition.
- Relief of symptoms of a named disease, disorder, or condition.

**Low Risks:**

- Health maintenance, including nutritional support.
- Vitamin or mineral supplementation.
- Relief of symptoms (not related to a named disease, disorder, or condition).



### 2.2.3 Health Product Claims:

A product would be considered as a health product if it meets the above statutory definition. Also, the finished label of the product presentation “It is necessary to take the view that a product is presented for preventing disease”.

#### **Claim To restore, correct, modify:**

- Claims to “protect” or “avoid” May perceived as having much the same meaning as “prevent”.
- The claim about “maintain” or “help to maintain” or “support” health or a healthy lifestyle would not be perceived as having much the same meaning as “prevent”.
- General well-being claims describe general well-being and a general disease such claims are allowed only if they also say how widespread the disease where the claim is truthful and not misleading.
- 'Function Health Claims'
  - Relating to the growth, development, and functions of the body.
  - Referring to psychological and behavioral functions
  - Slimming or weight-control
- Claims to relieve symptoms, or to cure, or to provide a remedy or heal a specific disease or adverse condition of body or mind will also be regarded as medicinal claims not regarded as health claim.

Note: Claims cannot state that a product does not have any side effects. Therefore, a term such as "100% safe" is not permitted. The fact that a product is natural should not suggest that is 100% safe

Note: Claims should not imply that the use of health supplements can affect one’s love life or relationship with others. Therefore, they cannot imply inducing sexual virility, managing sexual weakness, or conditions such as premature ejaculation and erectile dysfunction.



#### **2.2.4 Cosmetics Claims:**

A product is classified as cosmetic product if it meets the above statutory definition. Also:

- Cosmetic products should not contain medicinal or therapeutic claims, and they should not have a significant physiological effect.
- The product should not be presented as treating or preventing disease.

Note: Please refer to SFDA.CO/GSO 2528/2016; Cosmetic products – Technical Regulation of cosmetic and personal care products claims (GCC Standardization Organization (GSO) for more details and examples

#### **2.2.5 Medical Devices Claims:**

A product would be considered as a medical device product if it meets the above statutory definition. In the following summary of medical device claim in definitions

- Diagnosis
- Prevention
- Monitoring
- Treatment
- Alleviation of Disease
- Compensation for An Injury Or Handicap
- Investigation of The Anatomy
- Replacement A Physiological Process
- Modification A Physiological Process
- Support A Physiological Process
- Life Support
- Control of Conception
- Disinfection of Medical Devices

Note: Please refer to Appendix B (Examples of the claims that not to be considered as a medical devices)

Note: Medical claims in medical devices are directly dependent on scientific evidence to support such claims. If the claims are not proven, then the claims are unaccepted.



## Appendix

### Appendix A: Illustrative examples on acceptable medical claims of some of the allowed herbs and medicinal plant

Claims / uses	Warnings	Scientific name
For the temporary relief of sleep disturbances due to symptoms of mild anxiety based on traditional use only. For the temporary relief of symptoms of mild anxiety, based on traditional use only. (Valerian, Lemon Balm)		Lemon Balm
for the relief of muscular aches and sprains, based on traditional use only		Ruta
For relief of the symptoms associated with premenstrual syndrome	It is preferred not to be used by pregnant women	Vitex agnus-castus
For the relief of excessive sweating associated with the menopause based on traditional use only For the relief of excessive sweating associated with menopausal hot flushes, including night sweats based on traditional use only.		Sage Leaf ( <i>Salvia officinalis</i> L.)
For the temporary relief of symptoms associated with stress such as fatigue, exhaustion and mild anxiety based on traditional use only.		German Chamomile flower



For the relief of flatulence, bloating and mild upset stomach, based on traditional use only.		Roman Chamomile flower
For the relief of minor muscular and articular pain and minor peripheral circulatory disorders.		Rosemary oil
For the relief of coughs, such as chesty coughs and dry, tickly, irritating coughs and catarrh based on traditional use only.		Thyme
For symptomatic relief of minor digestive complaints such as indigestion, dyspepsia, feeling of fullness, flatulence and temporary loss of appetite based on traditional use only.		Ginger ( <i>Zingiber officinale</i> ROSCOE) rhizome
For the symptomatic relief of minor digestive complaints such as dyspepsia, flatulence and stomach cramps, based on traditional use only		Peppermint Oil ( <i>Mentha x piperita</i> L.)
For the relief of rheumatic aches and pains, based on traditional use only		Celery Seed ( <i>Apium graveolens</i> L.)
For the temporary relief of fatigue, weakness and exhaustion, based on traditional use only.		Ginseng Root ( <i>Panax ginseng</i> C. A. Meyer)
As an aid to slimming as part of a calorie-controlled diet, based on traditional use only.	It is preferred not to be used by pregnant and lactating women due to lack of information on its safety	Bladderwrack Thallus ( <i>Fucus vesiculosus</i> L. or <i>Fucus serratus</i> L)



To increase the amount of urine for the purpose of flushing the urinary tract to assist in minor urinary complaints. This is based on traditional use only	This herb is not safe for long term. Also, it is preferred not to be used by pregnant and lactating women due to lack of information on its safety	Horsetail herb
To relieve the symptoms of Raynaud's syndrome and tinnitus, based on traditional use only.		Ginkgo Leaf ( <i>Ginkgo biloba</i> L.)
For the symptomatic relief of coughs based on traditional use only.		Liquorice Root ( <i>Glycyrrhiza glabra</i> L.)
For the temporary relief of sleep disturbances due to symptoms of mild anxiety. For the temporary relief of symptoms of mild anxiety and to aid sleep.		Valerian Root ( <i>Valeriana officinalis</i> L.)
For the temporary relief of toothache, based on traditional use only.		Clove oil ( <i>Syzygium aromaticum</i> (L.)



**Appendix B: Examples of the claims that are NOT considered to be medical devices:**

Products category	Examples of Claims	Notes
Disinfectants	<ul style="list-style-type: none"><li>• Purifying and Humidifying air environmental cleaning</li></ul>	
Massage Tools	<ul style="list-style-type: none"><li>• Relaxing Massage</li></ul>	
Face Mask	<ul style="list-style-type: none"><li>• Preventing Bacterial Multiplication</li><li>• Preventing Dust, Fluid and Smoke</li></ul>	
Face Shield	<ul style="list-style-type: none"><li>• Preventing Dust and Fluid</li></ul>	
Gloves	<ul style="list-style-type: none"><li>• Preventing Chemical Fluid</li></ul>	
Sterilization Gates	<ul style="list-style-type: none"><li>• Whole Body Sterilization</li><li>• 360 Degree Sterilization</li></ul>	
Radiation Lead Glass	<ul style="list-style-type: none"><li>• Protection for Staff in X-Rays Room</li></ul>	
Coverall	<ul style="list-style-type: none"><li>• Protection Against Danger Dust</li><li>• Protection Against Chemical Liquid</li></ul>	





## References

- SFDA's List of Allowed Herbs and Medicinal Plants. SFDA. Oct 2019. Available at: [https://beta.sfda.gov.sa/sites/default/files/2020-06/List\\_of\\_herbs\\_medicinal\\_plants\\_allowed.pdf](https://beta.sfda.gov.sa/sites/default/files/2020-06/List_of_herbs_medicinal_plants_allowed.pdf)
- MHRA's Herbal medicines granted a traditional herbal registration Guidance. Dec 2019. Available at: <https://www.gov.uk/government/publications/herbal-medicines-granted-a-traditional-herbal-registration-thr/herbal-medicines-granted-a-traditional-herbal-registration>
- A GUIDE TO WHAT IS A MEDICINAL PRODUCT. Nov 2012 Available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/380280/guide\\_8\\_what\\_is\\_a\\_medicinal\\_product.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/380280/guide_8_what_is_a_medicinal_product.pdf)
- Label claims for conventional foods and dietary supplements June 2018 Available at: <https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements#:~:text=Health%20claims%20describe%20a%20relationship,disease%20or%20health%2Drelated%20condition.>
- SFDA's product classification guidance: <https://old.sfda.gov.sa/ar/oper/Documents/SFDAProductsClassificationGuidance.pdf>
- GCC Standardization Organization (GSO), GSO-2528-2016-E
- Requirements for Health and Nutrition Claims, SFDA.FD 2333 / 2019