الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guidance for Borderline Products Classification

Draft

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Guidance for Borderline Products Classification

Draft

Saudi Food & Drug Authority

Kingdom of Saudi Arabia

Please review and send your comments and suggestions within 60 days of publication to

Classificationfeedb@sfda.gov.sa

Saudi Food & Drug Authority

Vision and Mission

الرؤية والرسالة

Vision

To be the leading regional regulatory authority for food, drugs and medical devices with professional and excellent services that contributes to the protection and advancement of the health in Saudi Arabia.

الرؤية

أن تكون هيئة رائدة عالمياً تستند إلى أسس علمية لتعزيز وحماية الصحة العامة

Mission

To ensure the safety of food; the safety, quality and efficacy of drugs; and the safety and effectiveness of medical devices, by developing and enforcing an appropriate regulatory system.

الرسالة

حماية المجتمع من خلال تشريعات ومنظومة رقابية فعالة لضمان سلامة الغذاء والدواء والأجهزة الطبية ومنتجات التجميل والمبيدات والأعلاف

Document Control

Version	Author	Date	Comments
DRAFT	Products Classification Department	08/11/2020	Initial draft for public comments

Table of Contents:

1. Introduction

1.1 Objectives

This guidance addresses the Saudi Food and Drug Authority's (SFDA) current understanding of borderline products; and helps to clarify the areas where the borderline exists between two or more regulations. Moreover, this guidance explains the classification criteria and the approach to determine the most appropriate regulatory path when there is doubt or difficulty in classification.

1.2 Background

The SFDA is the responsible authority for licensing and regulating products such as drug, medical devices, food and cosmetics. This is in accordance with the existed legislations and requirements. In most cases, the classification of such products is clear due to the product's characteristics and the way it meets SFDA's statutory definitions.

However, in borderline cases, the classification may not be clear from the outset. This could be due to several reasons such as the difficulty in meeting the classification criteria stated in the SFDA's Products Classification Guidance, another reason could be due to the complexity of the product that makes it hardly compatible to the scope of regulations.

However, the view expressed in this guidance is to help SFDA's stakeholders on the classification of their borderline products, achieve a greater transparency on classification activities, and protect product's consumers by bringing the product under the most appropriate regulatory framework.

1.3 Scope

This guidance document pertains to a product or category of products that is under the responsibility of each sector within SFDA regulation.

1.4 General Principles

Borderline products are classified by submitting a classification application to the Products Classification Department (PCD) via the electronic-Products Classification System (ePCS), the classification is based on different classification criteria such as those

mentioned hereinafter in this document in conjunction with the relevant regulations and classification guidelines. In case of very difficult situations, the PCD is entitled to submit the classification and regulation recommendations to the Joint Advisory Committee for Products Classification (JACPC) to take the appropriate decision regarding the regulatory path.

1.5Definitions

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.

Dietary supplement: Products that are used to supplement the normal oral feeding diet, It is intended to boost a specific or several food element in the diet or for their non-therapeutic nutritional or physiological effects, it is often concentrated and taken in small amounts.

Dosage form: The finished formulation of pharmaceutical product, e.g. tablet, capsule, suspension, solution for injection, suppository.

Drug: A) Any Pharmaceutical Product manufactured in a pharmaceutical dosage form and contains one or more of active substance used externally or internally in treatment of a disease in human, or prevent the disease. *OR*

B) 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

Food: Any substance whether processed, semi-processed or unprocessed, which is intended for direct human consumption or to be used in manufacturing, preparing or treating a foodstuff.

Herbal Product: A) Any finished labeled medicinal products that contain as active ingredients aerial or underground parts of plants, 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. *OR*

B) Any plant or herb manufactured in a pharmaceutical dosage form, and presented with a medical claim.

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

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

A. 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;

B. 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. Drug-Food Borderline Product

This category of products is the most common type of borderlines, and it may include different cases such as the following: (please, refer to Appendix 1 for more examples):

- Drug substance and/or medicinal herbs that are presented in food form with medical claim.
- Products containing food ingredients in pharmaceutical dosage form including but not limited to capsule, tablet, drop, powder for suspension, inhaler…etc.
- Food products presented with medical or unacceptable health claim.
- Food products containing active pharmaceutical ingredient such as medicinal herb or medicinal substance.
- Dietary supplement with a therapeutic effect.

2.1 Classification Criteria:

The statutory definition:

The statutory definitions of drug products have two non-cumulative conditions (the first condition, is the pharmaceutical dosage form, and the second one is the intended use of treating, preventing diseases and/or affecting the structure or function of the body), and the product needs to **fulfill one condition** to be classified as a drug.

However, foodstuff, as per the definition, depends mainly on the primary claim, products consumed generally for their nutritional value, hydration, taste, flavor, or as part of diet..etc., are considered as food, unless they contain a medicinal substance. Moreover, products primarily used in manufacturing, preparing, or treating food are regarded under food sector.

The SFDA considers the following factors to determine if the product satisfies the above conditions:

1. The intended use (claim) made on the labeling, websites, promotional/advertisement materials, etc.

- Claims (implicit or explicit) or reference to a medical condition, symptoms, alleviation and/or prevention...etc., of a disease are considered as medical claims. Thus, products with these claims will be classified under drug jurisdictions, as they satisfy the second condition of the drug definition.
- Certain health claims to "maintain or help support health...etc." are acceptable under food regulation; however, claims made on food products should comply with the SFDA Requirement for Health and Nutrition Claims.

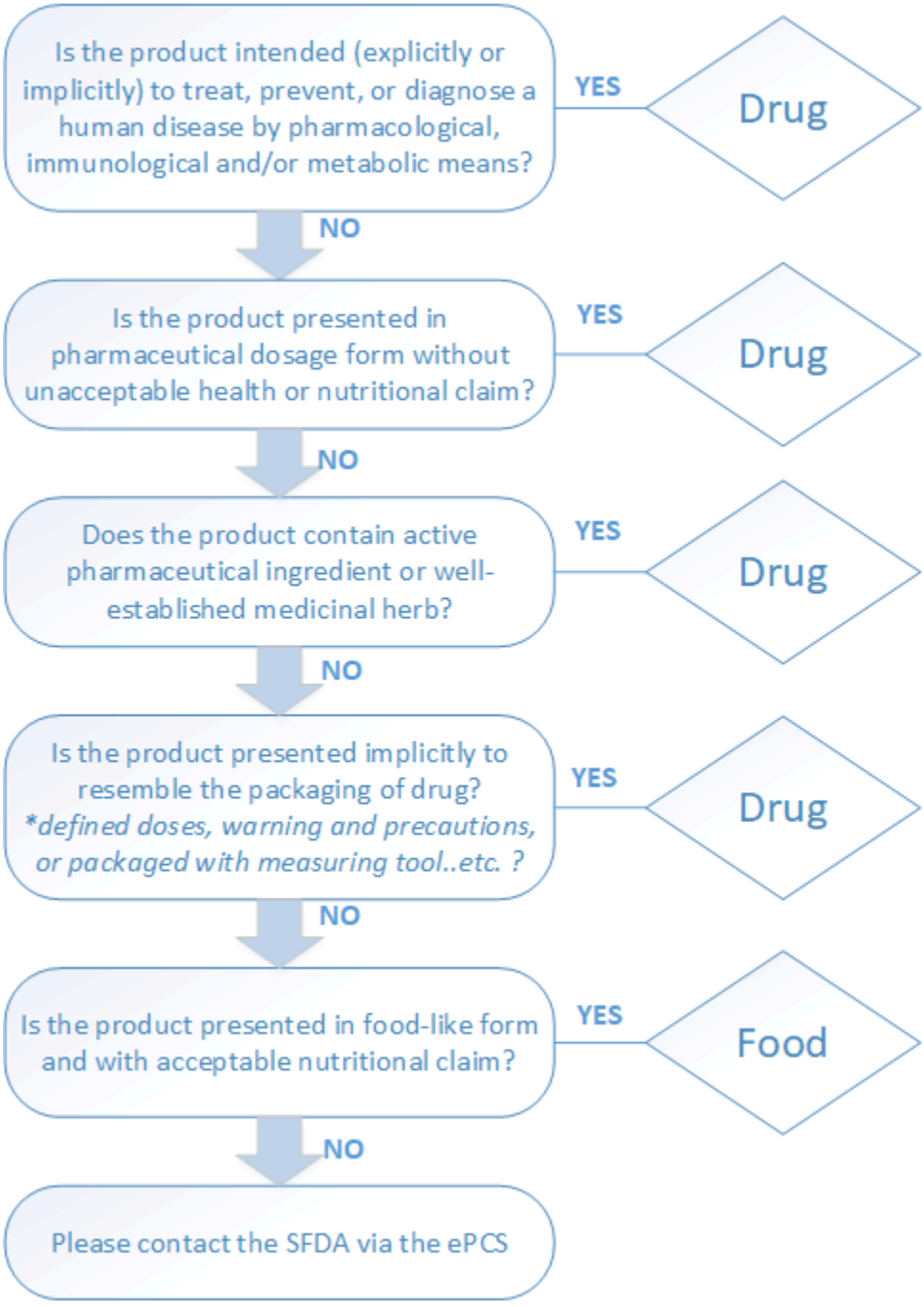
Note.1
Please refer to SFDA.FD 2333 'Requirement for Health and Nutrition Claims"

2. <u>The compositions of the product, and the way they affect the body</u>
    - SFDA reviews all available evidence related to the compositions, and the mode of action where such ingredients affect the body to achieve the intended use.
    - For example, there are certain active ingredients that are approved by the SFDA to be drug substances, while others have well-established and published scientific evidence to demonstrate a pharmacological, immunological, or metabolic action at certain level or concentration.
3. <u>The product form</u>
    - Although there are some forms that are considered typically to be pharmaceutical forms, such as injections, suspensions, capsules, tablets, inhalers..etc., some forms are considered borderline especially liquids and powders. However, there are some factors that could help supporting the determination of the dosage form as "pharmaceutical dosage form", e.g. the presence of a measuring tool, or in case that the product is packaged and labeled with dosing instructions that allow it to be consumed in controlled doses,..etc.
    - Foodstuff or dietary supplements such as minerals or vitamins that are presented in pharmaceutical dosage form will be regarded as drug as they satisfy the first condition of the drug statutory definition.

- A drug substance and/or medicinal herb with well-known medicinal effect that are presented in food like form will be regarded as drug products as they meet the second condition of the definition.

Note.2
"SFDA Products Classification Guidance"
"SFDA's Registered Drugs and Herbal Products List"

CLASSIFICATION FLOWCHART FOR FOOD-DRUG BORDERLINE PRODUCTS



3. Borderline between cosmetics and other legislations

This could include but is not limited to:

- Moisturizing ointment making claims of reliving joint pain
- Skin cleaning wipes impregnated with an antiseptic substance
- Oral care products with claims of treating gum conditions.
- Skin peeling products that significantly affect the normal skin physiology.

Note.3

Please, refer to Appendix 1 for illustrative examples.

3.1 Classification Criteria:

The statutory definition:

The statutory definition of cosmetic is based on two cumulative conditions (the first condition, is the site of application, and the second is the primary intended purpose). A product needs **to fulfil both conditions** to be regarded as cosmetic. Moreover, cosmetic products must comply with all safety, technical and any product's specific standards (if available).

The SFDA considers the following factors to determine if the product satisfies the above conditions:

1. The intended use (claim) made on the labeling, websites, promotional/advertisement materials, etc.
   - The proposed claim(s) for cosmetic product must be in relation to the cosmetic function i.e. "*cleaning the external parts of the body, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors*."
   - There are some ingredients known to have both medicinal and cosmetic uses, for these ingredients to be regarded under cosmetic legislation, a product must not presented (implicitly or explicitly) to treat, diagnose, and/or prevent a disease.

- For products having a secondary health claim to the primary cosmetic purpose, they will be classified as cosmetic product. For example, a cosmetic product containing an ingredient functioning as a preservative or a broad (non-specific) antimicrobial secondary to the main cosmetic purpose.

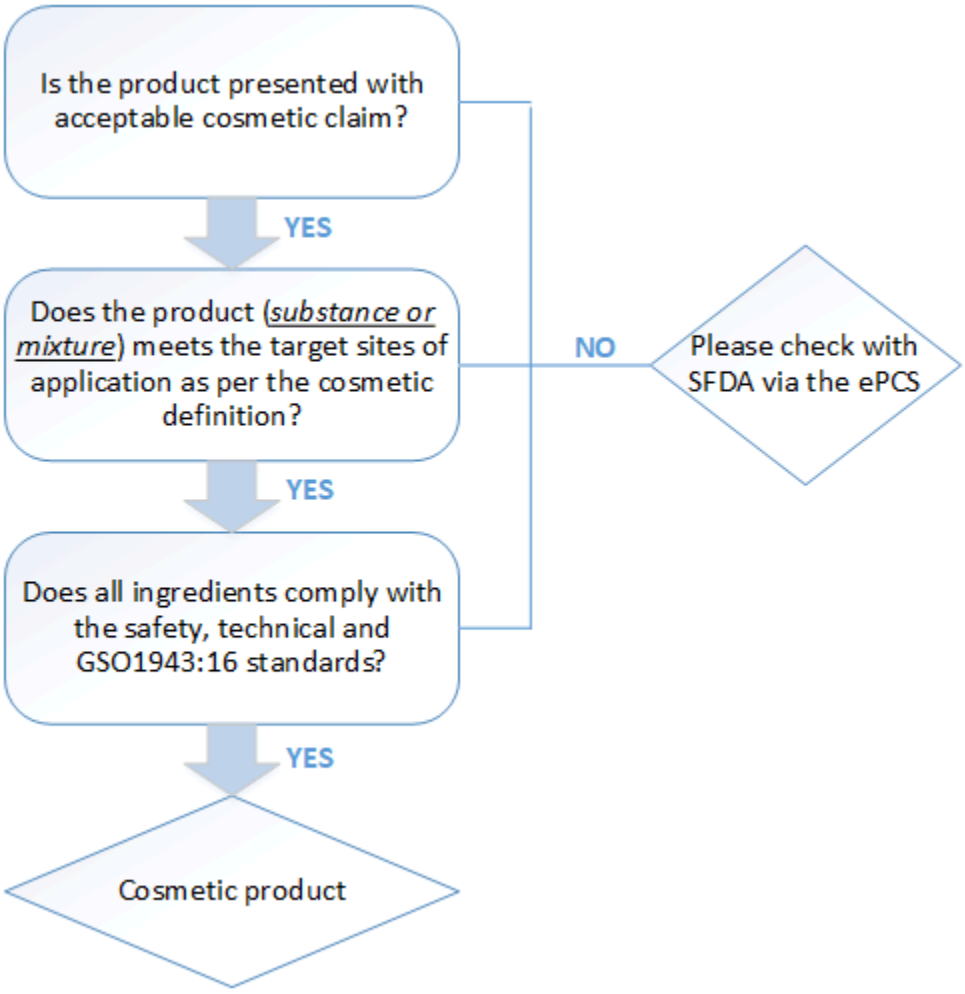
2. <u>The compositions of the product, and the way they affect the body</u>
   - Some products have the ability to affect the physiological function of the body, for example, skin care products that may affect the physiological function of the skin cell, keeping them in a good condition and to some extent, changing the skin appearance. This insignificant physiological mode of action does not usually exclude the product from cosmetic legislation.
3. <u>The product format:</u>
   - As per the statutory definition of cosmetic, products intended to be placed in contact with nasal mucosa, eye, ear, as well as products ingested, injected or used for rectal or internal genital organs are not cosmetic products.
   - Products used for oral hygiene care especially those presented in forms need to be swallowed to achieve their cosmetic purpose, they will not be considered as cosmetics if the swallowing is ancillary, for example, breath-mint or deodorizing lozenges. However, if the swallowing is incidental to the cosmetic purpose, (for example, breath spray and/or mouthwash), then the product will be regarded as cosmetic.

Note.5

Please refer to the following:

- The classification criteria of cosmetic product in “SFDA Products Classification Guidance”,
- “SFDA’s Listed Cosmetic Products”
- SFDA.CO/GSO 1943:2016 Safety Requirements of Cosmetic and Personal Care Products
- SFDA.CO/GSO 2528:2016 Cosmetic product – Technical Regulation of cosmetic and personal care products claims

CLASSIFICATION FLOWCHART FOR BORDERLINE BETWEEN COSMETICS AND OTHER PRODUCTS



4. Borderline between medical device and other legislations

This could include but is not limited to:

- Product presented to treat sore throat by physical meaning and that contains a medicinal herb
- Wound irrigation solution with antimicrobial substance
- Tooth whitening product to be placed inside the tooth

4.1 Classification Criteria:

The statutory definition:

Based on medical devices statutory definition mentioned above, a product will be regulated under medical device sector if it meets the two cumulative conditions stated below:

- The claim or the primary intended purpose
- The mode of action (*physical or mechanical*) by which the product achieves its claim

The SFDA considers the following factors to determine if the product satisfies the above conditions:

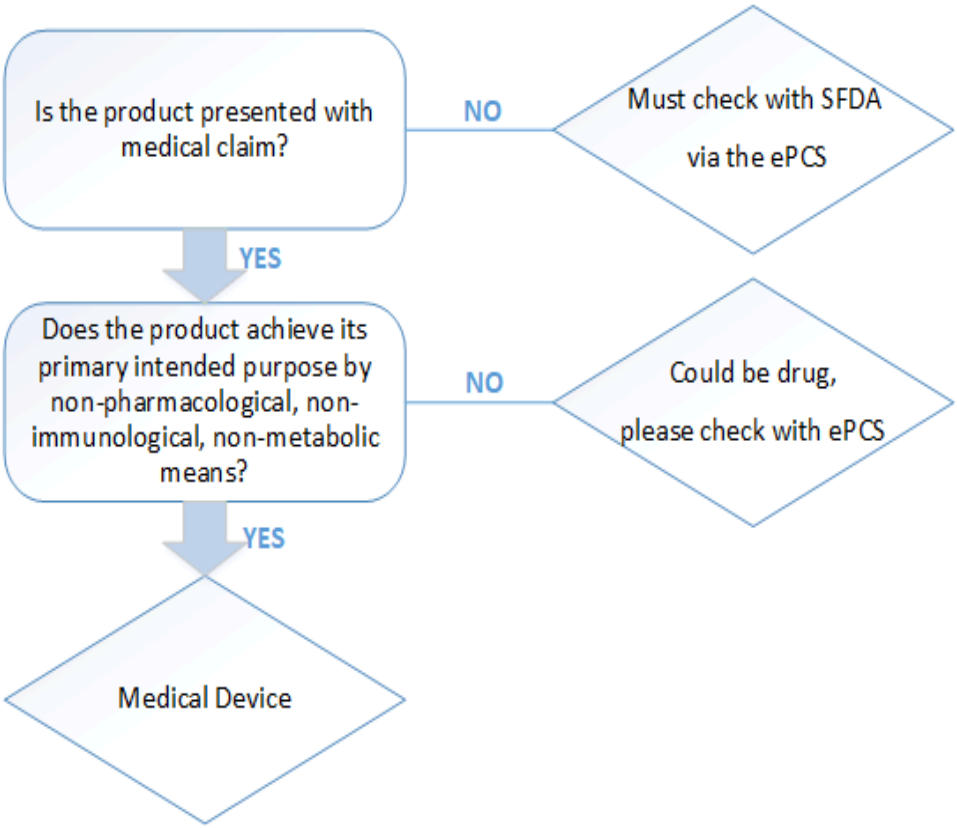
1. <u>The intended use (claim) made on the labeling, websites, promotional/advertisement materials, etc.</u>
    - In general, a product with medical claims such as to treat, diagnose, and/or prevent a disease is either drug or medical device. For medical device, the product must not achieve its intended purpose by pharmacological, immunological or metabolic means.
    - There are certain products might be presented with cosmetic claims such as skin pealing, skin caring, or tooth whitening, these products could fall under the medical device regulation depending on the product's full characteristics and the primary mode of action.

2. The compositions of the product, and the way they affect the body
    - Some medical devices may contain a drug or a herbal substance that acts on human body by ancillary mode of action; such products will not be excluded from medical device regulation. For example, anti-lice products containing natural source oils that act by electro-acting or suffocating the lice or its egg.
    - Certain products that are without an intended medical purpose could be registered as medical devices based on primary the mode of action as well as the classification rules for medical devices.
    - However, it is highly important to determine the most appropriate regulatory path on case-by-case basis, taking into account, the full product's characteristics and classification criteria.
3. The product formats
    - For products presented in pharmaceutical dosage forms, these products will not be regarded as medical devices unless they satisfy both conditions of the medical device's statutory definition. For examples, products presented to be ingested in capsule or tablet forms, for treating obesity, and which act by physical means such as bulking agents.

Note.3

Please, refer to SFDA Products Classification Guidance.

CLASSIFICATION FLOWCHART FOR BORDERLINE BETWEEN MEDICAL DEVICE AND OTHER PRODUCTS



Appendix 1

The Illustrative Examples of Borderline Classification Decisions

Category 1. Drug-Food Borderline	
Product	**Product Description and Classification**
Psyllium Husk (ispaghol) Powder	The product contained Psyllium seed husk in powder form. It was regarded under food regulation as dietary fiber because it was presented as dietary fiber without any unacceptable health or food claim. The Psyllium husk may have food or medicinal uses, classification will be depending on the intended use, the way the product is promoted to consumers, and the proposed claims on package, and or manufacturer's website..etc.
Probiotic and prebiotic sachet	This product contained a combination of probiotic, prebiotic and kimchi extract in powder dosage form. The product presented as food supplement. However, it was regarded under drug regulation as health product due to the claims of preventing tooth decay, the product packaged and labelled with dosing instructions for children and people who need to help prevent tooth decay. Moreover, the product was promoted with graphics showing a tooth behind a shield with what would associated with a health teeth and a protection from tooth decay.
Senna tea bag	The product Classified under drug legislation as it met the first condition of drug definition, where it contains a well-known medicinal herb with well-established evidence and history of use as laxative to treat constipation
Psyllium Husk sachet (Seed from Plantago ovata)	The product contained Psyllium seed husk in powder form. It was regarded under drug regulation as herbal products because it was presented with medical claims as an effective remedy for constipation (laxative) and to remove all toxins and clears the passage for the movement of food through the intestines in the stomach.
Lactium (milk protein (casein) hydrolysate)	The product classified as health product for registration as it packaged and labelled with dosing instructions for pediatric and this is considered as an implicit references to pharmaceutical dosage form
Omega 3 syrup	The product classified as health product for registration as it packaged and labelled with dosing instructions for pediatric and

	this is considered as an implicit references to pharmaceutical dosage form
Collagen hydrolyste , ascorbic acid and rosehips powder sachet	The product classified under drug regulation as it packaged and labelled with claims of protection, and improvement of joint performance. It was also promoted with graphics showing a man running with what would associated with a joint flexibility, protection and comfort symbol
Coffee mix with collagen, glutathione and l-carnitine	The product presented as an instant coffee to drink and enjoy, however, it was classified under drug regulation as herbal product for registration as it contains Senna leaves extract which is considered as a medicinal herb
Green tea complex with black pepper extract	The product was presented in capsule dosage form, moreover it was packaged and labeled with controlled dosing instructions, therefore, it was regarded under drug regulation
Herbal and honey tea bag	The product presented as a tea, it contained cassia leaves, cassia pods, and honey. It was regarded under drug regulation due to the claim as laxative and the dosing instructions on the outer package
Korean Red Ginseng Extract	The product was presented in a liquid form containing the red ginseng extract to be dissolved in water and drink as food product, it was regarded under food regulation according to GSO2210 Regulation
Asafoetida powder	Product was presented in powder form to be used as food spices for preparing food, it contained Asafoetida powder and was regarded under food regulation

Category 2. Borderline between Cosmetics & Other Legislations	
Product	**Product Description and Classification**
Eucalyptus oil and turpentine oil ointment with black seed	The claim on the product was for message and relaxing. The product was classified under drug regulation due to the claims that were presented on the company's website as treatment of muscle and joint pain, additionally, the ingredients have well established evidence of use in herbal medicine and as counterirritant to help relieving muscle and joint pain.
Breath mint lozenges with mouth refreshing claim.	The product was presented as mouth refreshing candies, and it contained food ingredients such as peppermint flavor, food additives, and others. However, to achieve its intended purpose, it needs to be dissolved orally and swallowed. Therefore, the product was classified as food product as it did not fulfill the cosmetic definition.
Hyaluronic acid, tea tree oil, THERMAL EYELIDS AND EYELASHES GEL	The product was presented as eye gel for hygiene, cleaning of eye, eyelids, eyelashes hydrating, and gives long-lasting protection with its contents tea tree oil, hyaluronic acid and sea buckthorn. The presentation of the product did not indicate any change or modification of a physiological function therefor it was classified as a cosmetic product
Tea tree oil and salicylic acid skin patch	Patch used for skin care for acne-prone skin and provides soothing & moisturizing to the skin. Therefore, it was regarded as cosmetic product as it met the cosmetic definition, (the product was not presented with medical or health claims a prevention or treatment of acne), moreover, ingredients used are within the acceptable limits for cosmetic standards and they do not restore, correct or modify physiological functions of the skin.
Mouthwash Tablets	The product was presented in tablet dosage form as antiseptic mouthwash, gargle and mouth rinse for use before, during, and after dental treatment. The product was labeled with instructions to place two tablets in warm water until fully dissolved and to ask patient to rinse around teeth and gums and spit out. Although the target area met the cosmetic definition, however, the products was regarded under medical device regulation as dental product as it was intended for antiseptic purposes

Nailner solution an Brush	The product was promoted as medical device, and it was presented as nailner solution with brush. The product intended to treat Onycomycosis (Fungal Nail Infections). Therefore, it cannot be qualified as cosmetic products. The mode of action is based on total saturation of the nail and lowering the pH the product by chemical action as it contains (lactic acid, ethyl lactate) which alters the local condition of the nail in the disadvantage of the fungus to allow the nail to recover from fungal infection. The product regarded under drug regulation according to the overall characteristics of the product, which mainly depended on the intended purpose to treat or to prevent fungal nail infections or other diseases, by chemical action.

Category 3. Borderline between Medical Device & Other Legislations	
Product	**Product Description and Classification**
Escin Suppository with menthol and vitis vinifera lipo extract	This product was presented as a low risk medical device for treatment of hemorrhoids; however, it was classified under drug regulation as the product achieves its intended purpose by the pharmacological action that is exerted by the product's compositions.
Disinfectant brush for hand scrub	The product was presented as antiseptic of hands and forearms with health skin of sanitary personal prior to surgery; it was classified under drug regulation because it met the first condition of the definition. Moreover, the product contained povidone-iodine, which exerts a chemical action on the body.
Artificial Saliva / Saliva Replacement products such as dispersible effervescent tablet, gel, liquids..etc.	The product was classified as medical device, as it was presented to lubricate the oral mucosa and substitute natural saliva for treatment of dry mouth and oropharynx (hypo salivation xerostomia), this is done through viscosity-increasing agents, such as cellulose derivatives as well as electrolytes.
Cough syrup with GRINDELIA	The product was presented as an adjuvant for treating dry and productive cough and irritation of the oropharyngeal mucosa, the company claimed that the product's mode of action was mechanical and it creates a protective layer that

ROBUSTAEXTRACT, PLANTAGO MAJOR LEAFEXTRACT, HELICHRYSUM ITALICUMEXTRACT	adheres to the mucosa ensuring hydration and counteracting irritation. However, after reviewing the documents, the product regarded under drug regulation as it contains several medicinal herbal extracts such as GRINDELIA ROBUSTAEXTRACT, PLANTAGO MAJOR LEAFEXTRACT, HELICHRYSUM ITALICUMEXTRACT and other ingredients, these substances are known traditionally to be used to relieve cough through chemical action which does not meet medical device definition.
Quaternary Ammonium compounds for surfaces disinfectant	The product was presented as hard surface disinfectant. However, It was regarded as medical device due to the claim of disinfecting surgical, medical and dental devices, which met the statutory definition of medical device.
Glycerin and liquid paraffin Cream	This cream was presented for the management of dry skin, remove conditions eczema and psoriasis. It was classified as medical device as it achieves its intended treating purpose by non-pharmacological, non-immunological, or non-metabolic means
Dimethicone (silicone) gel	It was presented as a patented lightweight self-drying silicone gel for the treatment of scars. It rapidly dries to form a flexible waterproof sheet which forms a protective barrier against, there are two actions and its classified as medical device
Ear hygiene, wax removal drop	Ear hygiene drop that was intended to remove earwax and prevent its recurrence. The product contained natural ingredients that work by soothing the earwax and removing it by self-cleaning. The product was classified as medical device as it met the medical device statutory definition and mode of action.

Appendix. 2

Comments on Borderline Products Classification Guidance

Please submit comments to the following E-mail: classificationfeedb@sfda.gov.sa			
SN	**Item No.**	**Item text**	**Proposed Amendment**
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