Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Guidance for Borderline

Products Classification

Guidance for Borderline Products Classification

Version 3.0

Operation Sector

Date of publication 08/11/2023 Saudi

Food & Drug Authority

Kingdom of Saudi Arabia

For comments on guidance:

Classificationfeedb@sfda.gov.sa

For products classification requests:

PCS@sfda.gov.sa

Saudi Food & Drug Authority
Vision and Mission

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.

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.

Document Control

Version	Author	Date	Comments
DRAFT	Products Classification Department	08/11/2020	Initial draft for public comments
2.0	Products Classification Department	08/11/2021	Final
3.0	Products Classification Department	08/11/2023	Final

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 as these cases shares combined characteristics of two or more regulation.

Therefore, 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.

1.5.Definitions

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.

Food Supplement: Used to supplement the normal diet, which contains ingredients, alone or in combination, that have a nutritional or physiological effect. They have different forms of packaging. A food supplements consists of one or mixture of the following components or others: vitamins, minerals, fatty acids, amino acids, enzymes, prebiotics and probiotics, collagen, dietary fibers, melatonin, propolis, pollen, herbs or food herbal extracts.

Dosage form: Physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient in individual doses

Drug: 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

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: 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: Any instrument, apparatus, implement machine, implant device, 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 diagnosis, prevention, monitoring, controlling, treatment or alleviation of disease or injuries or compensation for injuries. It is also used for investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life (Vital functions of a human being), control of conception or assist for that, disinfection of medical devices and supplies and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body. It 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.

Medical Supplies: Medical products and materials, used for treatment or diagnosis, or compensation, or straighten, or for handicapped cases, or other medical uses for human being, including medical gases.

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 I for more examples):

- Drug substance and/or medicinal herbs that are presented in food form with medical claim.
- 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:

Pharmaceutical drug product:

The statutory definition of pharmaceutical drug product has two cumulative conditions; the first one is the function and/or presentation of the substance, i.e. the substance is presented to have, and/or used for therapeutic effect of treating or preventing diseases. The second condition, is that the product, in order to its proper administration, must be manufactured in a physical manifestation to deliver the active ingredient(s) to the patient in individual doses.

A product needs to **fulfill both conditions** to be classified as a drug product.

Food Definition:

Food product, as per the definition, depends mainly on the primary intended use. For examples, products consumed generally for their nutritional value, hydration, taste, flavor, as part of diet as well as products primarily used in manufacturing, preparing, or treating food are considered as food, unless they contain an active medicinal substance or presented to have a property of a treating or preventing a disease.

SFDA considers the following factors to determine if the product satisfies the above conditions of the statutory definition:

1. **The primary intended use and/or claims made on the product's labeling, websites, promotional/advertisement materials, etc.**

Medical claims:

- In the context of the drug definition, depending on the overall presentation of the product, uses or claims including words, symbols, pictures, or any other means, to treat, prevent, alleviate or help with a disease and/or a specific symptom will be considered as med ical use. Thus, products with such uses or claims will be subject to drug regulations.

Nutrition claims:

- Generally, the SFDA view is that a food product has particular nutritional properties including but not limited to the content of energy, protein, fat and carbohydrates, as well as the content of vitamins and minerals. Claim that states, suggests, or implies the above values must be complies with all the necessary requirements (including restrictions & warnings) listed in the national standards /technical regulation list No. SFDA.FD 2333 "Requirements for Health and Nutrition Claims".

Health claims:

- Health claims are claims stating, suggesting, or implying that a relationship exists between product's constituent(s) and health, and can be divided into two types as functional or disease risk-reduction claims. Health claims could be acceptable in food regulations as long as they do not state or imply that the food product has a property to treat or prevent a disease, symptoms, or any other adverse conditions. In addition, the food product must not achieve its intended purpose (functional or disease risk-reduction) by any pharmacological, immunological or metabolic means.
- Moreover, in order to classify a product under food jurisdiction, the product must comply with the SFDA Requirement for Health and Nutrition Claims as well as any other SFDA or GSO technical/safety standards and requirements for food products. However, applicants who wish to make health claims on food products that are not covered by SFDA's technical regulations and specifications can submit a claim evaluation request to the SFDA Health & Nutrition Claim Committee.

Note.1

Please refer to:

- SFDA.FD 2333 "Requirement for Health and Nutrition Claims"
- Guideline for Submitting a claim Evaluation Request of Health and Nutrition Claims
- The SFDA General Rules for Products Claim

2.The compositions of the product, and the way they affect the body

- 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.

- In general, a product could be classified as pharmaceutical drug products if it contains any substance that exerts, or demonstrates a pharmacological, immunological, and/or metabolic function. For example, dietary supplements containing ingredients such as vitamins and/or minerals with concentrations above the upper limit of the total daily allowance, will be classified as pharmaceutical drug products as they satisfy the first condition of the drug definition.

3.The product form

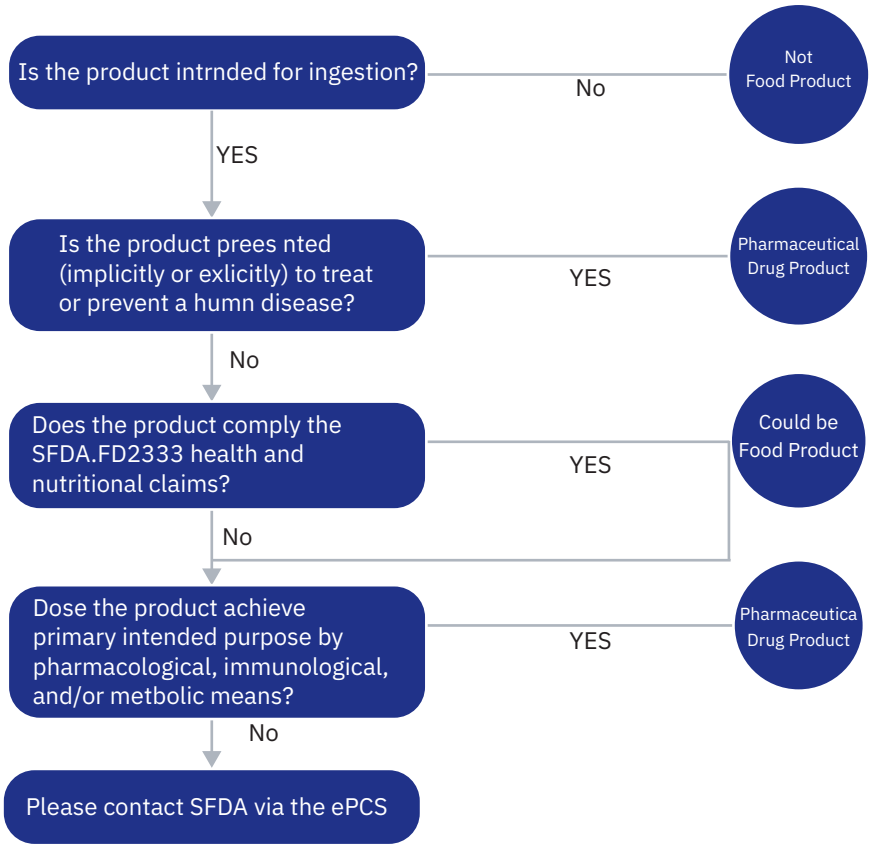
- Generally, products that are not intended for ingestion such as injection, topical, inhaler, vaping...etc. will be subject to drug jurisdictions. However, the product format is not always the solely criterion for classification and it should be reviewed on case-by-case bases. For example, in oral dosage forms such as powders or liquids, the product will be regarded under drug jurisdiction if it's intended, or presented to be used to treat or prevent a disease according to the statutory definition of drug product.

Note.2

Please refer to:

- "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 regulations

This could include but not limited to:

- Moisturizing ointment making claims of reliving joint pain
- Skin cleaning wipes impregnated with an active 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).

SFDA considers the following factors to determine if the product satisfies the above conditions of the statutory definition:

1. **The primary intended use and/or claims made on the product's 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." Therefore, products stating, suggesting, or implying to treat diagnose, and/or prevent a disease will be excluded from cosmetic regulation.
   - Products having a secondary health claim to the primary cosmetic purpose could be classified as cosmetic product. For example, a cosmetic product containing an ingredient functioning as a preservative or a broad (non-specific) antimicrobial effect secondary to the primary cosmetic purpose.

2. **The compositions of the product, and the way they affect the body**
   - In context of cosmetic definition, a substance or a mixture intended to change the appearance of the external parts of the body by affecting the physiological function in an insignificant way, does not usually exclude the product from cosmetic legislation. 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.

- Another example is products intended to be used as skin peeling through chemical action, depending on their composition and the way they affect the body, these products can be considered as cosmetic if they affect the top layer, or the dead cells of the skin surface.
- However, products containing a substance or mixture of substances that affects the body by exerting pharmacological, immunological and/or metabolic action could be considered as pharmaceutical drug product by virtue of the ingredient's function.

3.The product form

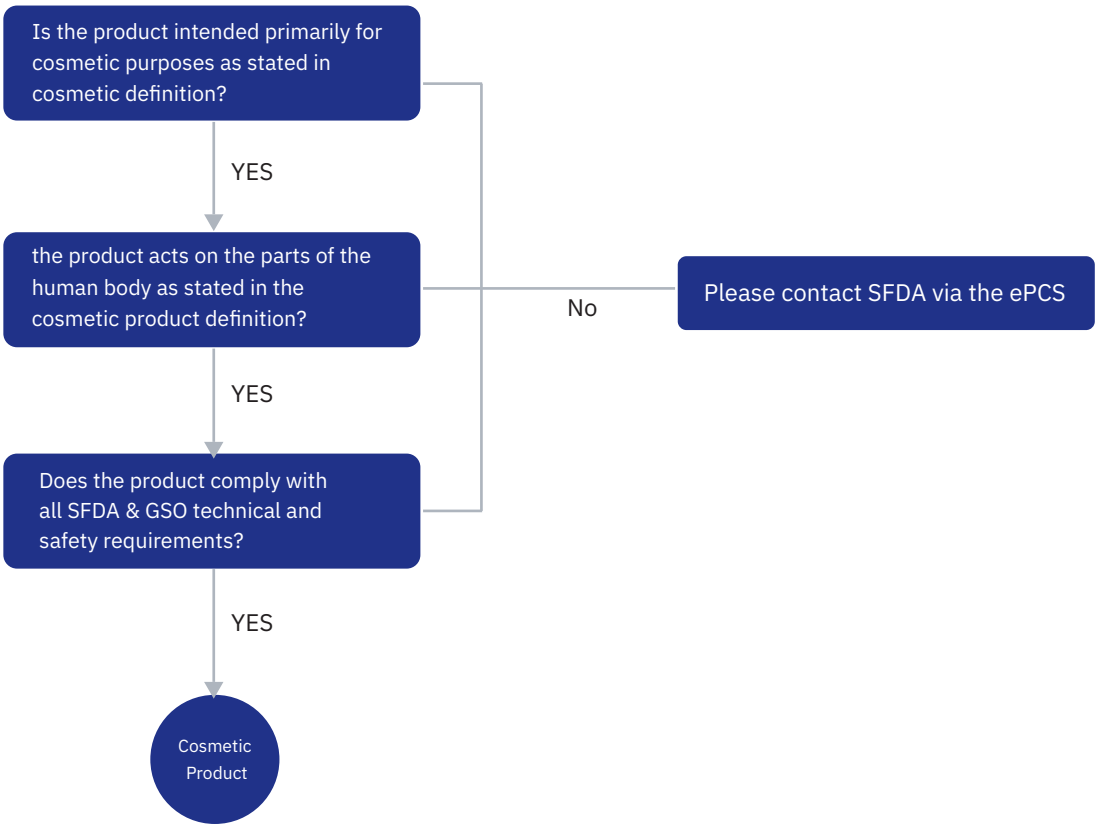
- As per the statutory definition of cosmetic, products intended to be placed in contact with nasal mucosa, eye, ear, as well as products ingested, injected or used for rectal or internal genital organs are not cosmetic products.
- Products used for oral hygiene care especially those presented in forms 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 could be regarded as cosmetic.

Note.4

Please refer to:

- The classification criteria of cosmetic product in "SFDA Products Classification Guidance",
- SFDA's Listed Cosmetic Products
- SFDA.CO/GSO 1943 Safety Requirements of Cosmetic and Personal Care Products
- SFDA.CO/GSO 2528 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 regulations

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 law if it meets the two cumulative conditions stated below:

- The primary intended purpose
- The primary mode of action by which the product achieves its intended use.

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

1.The primary intended use and/or claims made on the product's labeling, websites, promotional/advertisement materials, etc.

- In general, a product with medical claims to treat, diagnose, and/or prevent a disease is either a drug or a medical device. For medical device, the product must not achieve its primary intended purpose by pharmacological, immunological or metabolic means.
- There are certain products might be presented without intended medical purposes such as skin pealing, skin care, or tooth whitening products, these products may fall under the medical device regulation depending on the product's full characteristics such as the overall presentation, the primary mode of action, and/or compositions.

2.The compositions of the product, and the way they affect the body

- Applicants who wish to market their products as medical devices, will be required to show that their products meet the medical device definition, and the primary intended purpose is achieved by non-pharmacologic, non-immunologic, or non-metabolic means including mechanical, physical barrier, support, or replace of anatomy or physiological process.

- Products that may contain a drug substances including herbal or plant extracts may not be excluded from medical device regulation if these ingredients assist the primary intended purpose, and do not act on or in human body in a manner that is more than ancillary. For example, anti-lice products containing natural source oils that act by electro-acting or suffocating the lice or its egg.
- However, it is highly important to note that determining the most appropriate regulatory path will be taking on case-by-case basis, considering the full product's characteristics and classification criteria.

However, it is highly important to note that determining the most appropriate regulatory path will be taking on case-by-case basis, considering the full product's characteristics and classification criteria.

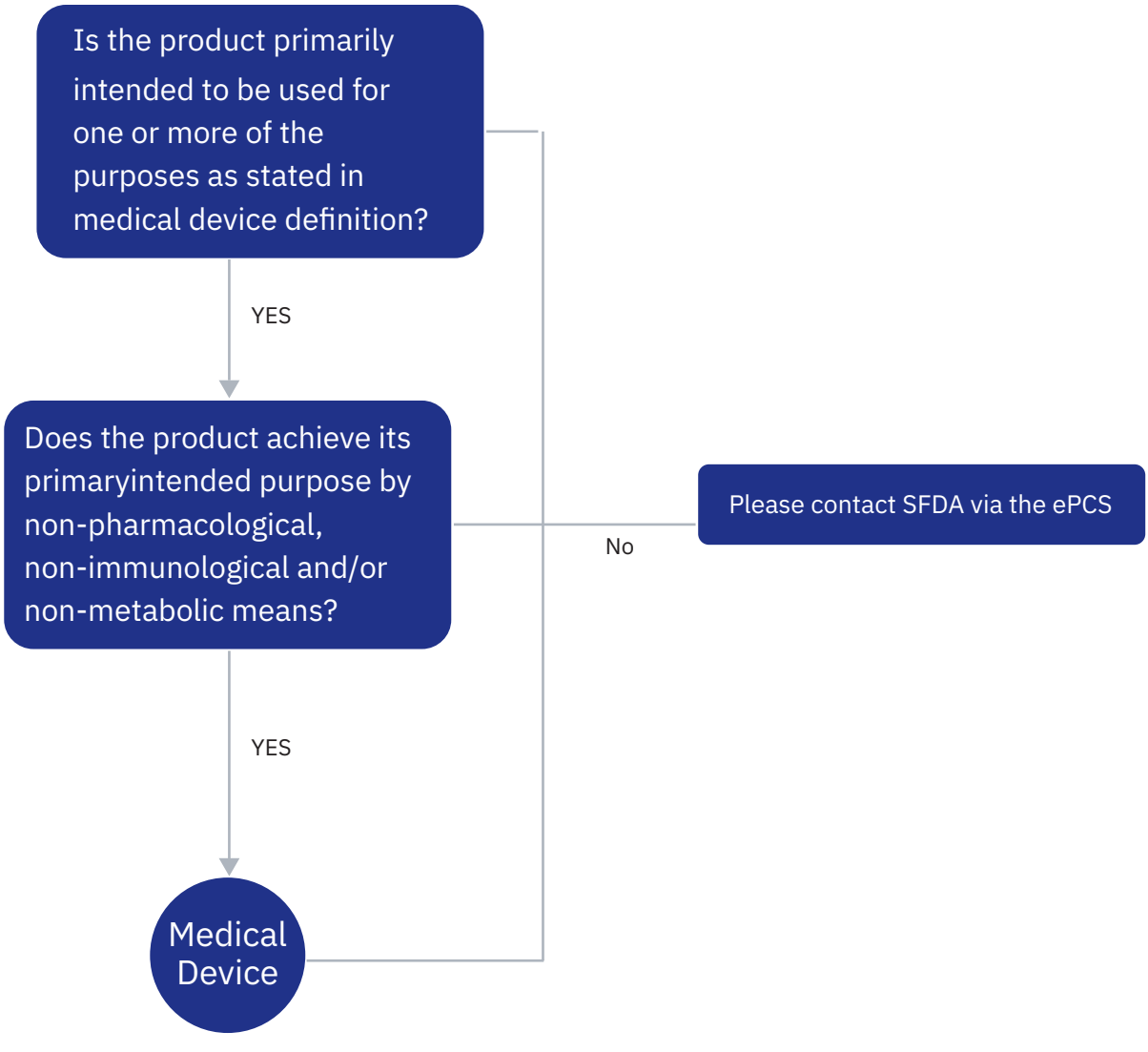
3.The product form

- Products presented in pharmaceutical dosage forms could be regarded as medical devices if they satisfy both conditions of the medical device's statutory definition, as the product format is not a unique criterion for drug products. 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.5

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. Psyllium husk may have food or medicinal properties, classification will be depending on the primary 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 was presented as food supplement containing a combination of probiotic, prebiotic and kimchi extract in powder dosage form. 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 that do not comply with the Labeling of Prepackaged Food stuffs.
Senna tea bag	The product was classified under drug legislation as it contained a well-known medicinal herb with well-established evidence and history of use as laxative to treat constipation.

Category 1. Drug-Food Borderline	
Product	**Product Description and Classification**
Psyllium Husk sachet (Seed from Plantago ovata)	The product contained Psyllium seed husk in powder form, and 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. Thus, the product was regarded under drug regulation as herbal drug product.
Ascorbic acid (vitamin C) effervescent tablet	The product was classified as food product as it satisfied the food supplement definition and complied with the technical standards of food products, besides it has a concentration within the daily allowed limit.
Omega 3 syrup	The product was presented as dietary supplement, it was classified as food product as it satisfied the food supplement definition.
Collagen hydrolyste , ascorbic acid and rosehips powder sachet	The product was classified under drug regulation as it was packaged and labelled with claims of protection, and improvement of joint performance and do not comply with the Labeling of Prepackaged Food stuffs.
Green tea complex with black pepper extract	The product was presented as an instant coffee to drink and enjoy, however, it was classified under drug regulation as herbal drug product for registration as it contained Senna leaves extract, which is considered as a medicinal herb.
Herbal and honey tea bag	The product was presented as tea; it contained cassia leaves, cassia pods, and honey. It was regarded under drug regulation due to its intended purpose as laxative and the dosing instructions on the outer package, which indicated implicitly that the product has health benefits.

Category 1. Drug-Food Borderline	
Product	**Product Description and Classification**
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 Ginseng Products Technical Regulation.
Asafoetida powder	Product was presented in powder form to be used as food spices for preparing food, it contained Asafoetida powder, and thus it was as food products.

Category 2. Borderline Between Cosmetics & Other Regulations	
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 candy, and it contained food ingredients such as peppermint flavor, food additives, and others. However, to achieve its intended purpose, the product was meant 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 significant change or modification of a physiological function therefore; it was classified as a cosmetic product.
Hyaluronic acid eye drops	The products was presented for eye moisturizing and lubrication. It was classified as medical device as it did not satisfy the cosmetic statutory definition.
Herbal and honey tea bag	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 any medical or health claims of prevention or treatment of acne), moreover, ingredients used were within the acceptable limits for cosmetic standards and they do not restore, correct or modify physiological functions of the skin.

Category 2. Borderline Between Cosmetics & Other Regulations	
Product	**Product Description and Classification**
Eucalyptus oil and turpentine oil ointment with black seed	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 was within the scope of the cosmetic definition, however, the products was regarded under medical device regulation as dental product as it was intended for antiseptic purposes by non-pharmacological, non-immunological, and non-metabolic means.
Topical immune health system	The product was presented as cosmetic product (impregnated wipes and foam) to be used topically in a variety of applications such as pre and post catheter insertion, and pre and post sexual intercourse. It was intended to promote daily urinary health in those suffering from recurring urinary tract infections, and to reduce the risks associated with cracks and openings of the skin. The product was classified under medical device regulation as it does not meet the cosmetic statutory definition.

Category 3. Borderline Between Medical Device & Other Regulations	
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. The product's primary mode of action was due to the povidone-iodine, and thus, it was classified under drug regulation.
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.
Quaternary Ammonium compounds for surfaces disinfectant	The product was presented as hard surface disinfectant. However, It was classified 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 such as 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.

Category 3. Borderline Between Medical Device & Other Regulations	
Product	**Product Description and Classification**
Dimethicone (silicone) gel	It was presented as a patented lightweight self-drying silicone gel for the treatment of scars. In order to achieve its primary intended purpose, the product rapidly dries to form a flexible waterproof sheet which forms a protective barrier, thus the product was 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 docusate sodium that works by dissolving the earwax and soothing removing it by self-cleaning. The product was classified as medical device as it met the medical device statutory definition and its mode of action.
Human antiseptic wipe containing chlorhexidine	This product was presented to be used on hands and skin surfaces to kill bacteria, viruses including (Covid-19), fungus, and molds. This intended purpose would be achieved by chlorhexidine. The product was classified under drug sector according the primary mode of action which is achieved by pharmacological action of the antimicrobial substance.
Antiseptic products with dual use	The products presented to be used as disinfectant for hands and medical devices. This product is classified to be regulated under both drug and medical device regulation.
Nailner solution and 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). The mode of action was based on total saturation of the nail and lowering the PH by metabolic action as it contained (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 metabolic action.

Appendix. 2

What is New in The Guidance for Borderline Products classification (version 3.0)?

The following table shows statements that added, deleted or replaced to the past draft issued on November 8, 2021:

Section	Current Amendment
Appendix 1	Updates on examples

Appendix. 3

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

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

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