Saudi FDA Products Classification Guidance

Version 5.0

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Version 5.0

Operation Sector

Saudi Food & Drug Authority

Kingdom of Saudi Arabia

Please review and send your comments and suggestions to Classification Feedback

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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

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1. Introduction

1.1. Objectives

This guidance presents the Saudi Food and Drug Authority's (SFDA's) current view on specific products or a category of products and whether it should be under the responsibility of Saudi Food and Drug Authority and particularly where the regulation may be on the borderline between two or more SFDA sectors. However, this guidance is not all-inclusive. Moreover, it does not provide any information about risk classes of medical devices.

1.2. Background

The SFDA consists mainly of four sectors: Food, Drug, Medical Devices and Operations. Each sector is responsible for distinctive products with different regulatory requirements. Therefore, the SFDA have been receiving a huge number of requests from the industry since its establishment. Most are relating to whether a product should be classified as drug, medical device or food. SFDA is also aware that other reasons behind this guidance include further identification of the subsequent scheme/path within each sector. Therefore, this guidance document has been issued to help SFDA stakeholders as well as SFDA staffs to classify products easily with a view to achieving greater consistency, transparency and quality of classification decisions relating to these products.

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.

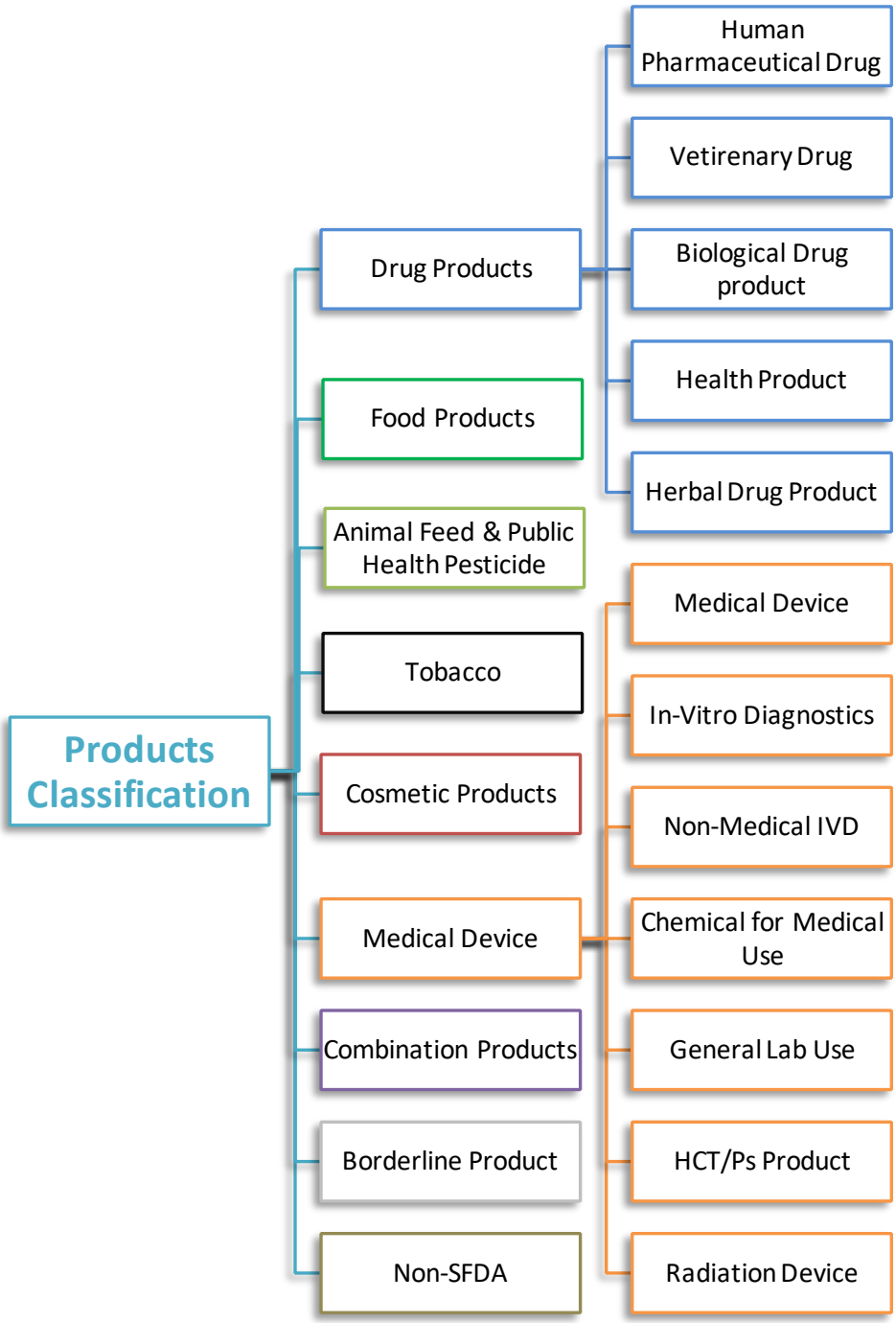
1.4. General Principles

SFDA will determine the classification of a product mainly on statutory definitions. Other definitions included in the associated regulated guidelines will also be considered. For example, a product may be classified as a medical device if it "does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means. If the product acts by such means, it will be classified as a drug. On the other hand, if the product contains a substance that has an ancillary action by assisting the product in achieving its primary intended actions, the product may be classified as device.

However, this is not always the case. Some products come at the borderline between two definitions (food/drug) or (drug/medical device). These products will be classified on a case-by-case basis.

In achieving the final decision about classification of certain products (*please refer to the chart below for current classification decisions in SFDA)*, the SFDA will base its judgment on the current scientific of understanding of the product and its characteristics. Moreover, the SFDA believes that global regulatory convergence is critical in achieving cooperation among regulatory bodies. Therefore, the authority will make its best endeavor in aligning its regulations with the common international practice and limit local requirements to where genuinely required or scientifically justified to protect the public health.

Chart.1: Classification Decisions in SFDA



1.5. Definitions

Animal Feed:

Any substances, single mixed processed or semi-processed, intended to feed animals, and used as a raw material or as an ingredient in the preparation of manufacturing or processing of feed originating from plant, approved animal source, or aquatic source.

Biological medicinal products:

Medicinal products derived from a variety of natural sources or produced by biotechnology methods and other cutting-edge technologies. They include a wide range of products such as vaccines, blood and blood components, allergenics, advanced therapy medicinal products (ATMPs), recombinant proteins and biosimilars.

Combination Products:

A product consists of two or more of items subject to different SFDA's jurisdictions in terms of regulatory path, marketing and/or manufacturing. It includes:

- Integrated combination product:
  - A product consists of two or more regulated components that are combined/integrated as a single product.
- Non-integrated combination product:
  - A product consists of two or more separated items that are contained in the same package. [Co-packaged combination product].
  - Any regulated product packaged separately where the labeling information refers to be used with another specific regulated product where both are required to achieve the intended purpose of use. [Cross-labeled combination product].

Compound feed:

Mixture of at least two feed materials, whether or not containing feed additives, for oral animal feeding.

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.

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 contain one or more of active substance used externally or internally in treatment of a disease in human, or prevent the disease.

Feed material:

Any products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved.

Feed Additives:

Components added to animal feed, which may or may not contain nutritional value, are intentionally added to the feed for technical, sensory, nutritional purposes and/or favorably improve animal production and performance or to satisfy the nutritional needs of animals.

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.

Food Supplement:

Products that are used to supplement the normal diet. Which contains ingredients, alone or in combination, may have a nutritional or physiological effect. Food supplements consists of one or more of the following components: vitamins, minerals, fatty acids, amino acids, enzymes, prebiotics and probiotics, collagen, dietary fibers, melatonin, propolis, pollen, herbs or food herbal extracts…etc

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.

Human cells, tissues, or cellular or tissue-bases products (HCT/Ps):

It means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, and cornea.

In-Vitro Diagnostic medical devices (IVDs):

Means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.

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.

Pharmaceutical 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

Premix:

Are mixtures of vitamins, mineral salts, amino acids, enzymes or others, as defined by the bylaws, intended to be added to feeds or water, often used as a carrier substance, used in feed manufacturing to enhance sufficiency.

Public Health Pesticides:

Any chemical substances, inorganic, organic or natural product or biological product containing elements of microorganisms used in the control of pests (including attractive and repellents substances).

Radiopharmaceutical Product:

A radioactive drug that can be administered safely to humans for diagnostic and therapeutic purposes.

Tobacco:

A Product obtained from a blend of *Nicotiana Tabacum* and / or *Nicotiana Rustica* species which has been flue – cured, air cured, fire cured or sweltered.

Tobacco Products:

Any products consisting wholly or partially of tobacco leaves as raw material which has been manufactured for the purpose of direct or non-direct smoking or absorption such as Cigarettes, Almeassel tobacco, Meassel Fruit flavored, cigar, as well as E-Liquids and Heated Tobacco Products which are used by Electronic Nicotine Delivery Systems (ENDS).

Veterinary Drug:

Any substance or mixture of substances manufactures, sold or represented for use in:

- The diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in animals.
- Restoring, correcting or modifying organic function in animals.

2. e-Product Classification System (PCS) Use Process

The ePCS provides three major services:

2.1. Company sign up service

2.2. Product classification service (online submission of the product classification application and classification decision)

2.3. Appeal service

Note:
- Performance target for sign up service is 1 working day
- Performance target for product classification service is 1 working day
- Performance target for appeal service is 3 working days

2.1.Company Sign Up Service (step by step procedure):

- Applicant shall go to e-Product Classification System (PCS) website https://pcs.sfda.gov.sa/Default.En.aspx
- Choose company login icon
- Click registration icon and fill out the form with all required information:
  - User name
  - Password
  - The name of the company in Arabic
  - The name of the company in English
  - The account manager name
  - The legal capacity
  - Copy of the authorization letter for the account manager certified from the chamber of commerce
  - Email address
  - Phone number
  - Cell – phone number
  - Commercial register number
  - After complete all the information click register

2.2.Product Classification Service

The applicant shall fill up the application form in the PCS. Once completed, a reference number will be generated to the applicant, to facilitate communication with SFDA. Upon receipt of the product

classification application, the submitted documents will be assessed and the final decision will automatically issued via the email, and can be viewed electronically via PCS.

2.2.1. Required documents for online classification application

- The purpose of using the product as provided by the manufacturer.
- User instructions as provided by the manufacturer.
- Product mechanism of action.
- Classification request letter indicating the name of the product and the name of the person responsible for the request with his contact information.
- Attach a product catalog with a clear image of the product.
- Attach the quality certificate from the manufacturer.
- Product registration certificate in the country of origin, if available.
- Identification card and product (artwork).
- Attach a product declaration of conformity (D.O.C).
- A classification letter from the manufacturer of the product indicating the product classification.

2.2.2. Classification Service Fees

- Submission fees (1000 SR) is mandatory in order to receive the classification decision
- A SADAD number will be generated automatically by the ePCS after submitting the online application

2.2.3. Application Status

Status	Meaning
Waiting Payment	Application is waiting for SADAD payment
Incomplete	Application stopped and pending on applicant feedback/update
Under Process	Application is in normal process at SFDA and no problem
Classified	Application request got final classification decision
Expired	Application request expiry due to late payment or response

2.2.4. Classification Decision

The applicant will receive the final classification decision via the email, and the decision can be viewed electronically through the PCS system.

The classification decision is considered valid for one year from the date of approval of the classification of the product. Obtaining the classification decision is not a marketing authorization; however, it requires the applicant to commite to the regulatory path stated on the decision.

2.3. Appeal Service:

The applicant has the right to appeal against the classification decision within 30 calendar days of receiving the final decision by submitting the regulatory or scientific justifications supporting the appeal.

3. Food

A product would be considered as food if it falls within the above-mentioned definition. Moreover, food product must not contain any medicinal ingredients, also it should not be marketed with medical claim, or in pharmaceutical dosage form. Food products may including the following categories:

3.1. Meat and meat products

3.2. Fish and Shell-Fish Products

3.3. Milk and dairy products

3.4. Processed fruits and vegetables products

3.5. Cereals, Pulses and Nuts and Their Products

3.6. Vegetable fats, Oils and Their Products

3.7. Water and Beverages, which do not contain ingredients with medicinal effect

3.8. Honey and foods that contain bee products such as royal jelly, bee pollen and propolis

3.9. Energy drinks

3.10. Food additives that are intended for food industrial uses

3.11. Food sweeteners

3.12. Electrolyte products (Oral Rehydration Solution)

3.13. Infant and baby foods such as cereal-based food, rusks, high protein food and others.

3.14. Foods for special medical purposes such as Nutritionally complete formula, Nutritionally incomplete formula, and Formulas for metabolic "genetic" disorders in patients over 12 months

3.15. Proteins, Carbohydrates and Amino acids products that are used as food supplement

3.16. Vitamins and minerals supplements with concentrations equal or below the upper concentration limit provided in the General Rules for Products Containing Vitamins and Minerals

3.17. Lozenges, which do not contain unacceptable claim or any ingredient with medicinal effect, and the concentration individual ingredients must not exceed the maximum value permitted as

follows:

- Menthol must not exceed the maximum value permitted of lower than 5 mg as single serving size, and to a maximum daily serving of 50 mg
- Eucalyptus oil of lower than 0.5 mg as single serving size

3.18. Collagen products that may contain vitamins and minerals, and must not exceed the maximum daily serving of 10 g

3.19. Food products that contain Moringa leaves

3.20. Novel foods, which do not contain ingredients with medicinal effect

3.21. Prebiotic and Probiotic for industrial use

3.22. Food products which contain fish oil

3.23. Fibers products

3.24. Sports food such as sports drinks, products in powder forms that are intended for sports people and persons who exercise to achieve specific nutritional or functional support

3.25. Weight management products

3.26. Glucosamine that is in concentrations lower than 1000 mg/day

3.27. Chondroitin sulfate that is in concentrations lower than 900 mg/d

3.28. Para-aminobenzoic acid that is in concentrations lower than 1200 mg/d

3.29. Hyaluronic acid that is in concentrations lower than 150 mg/d

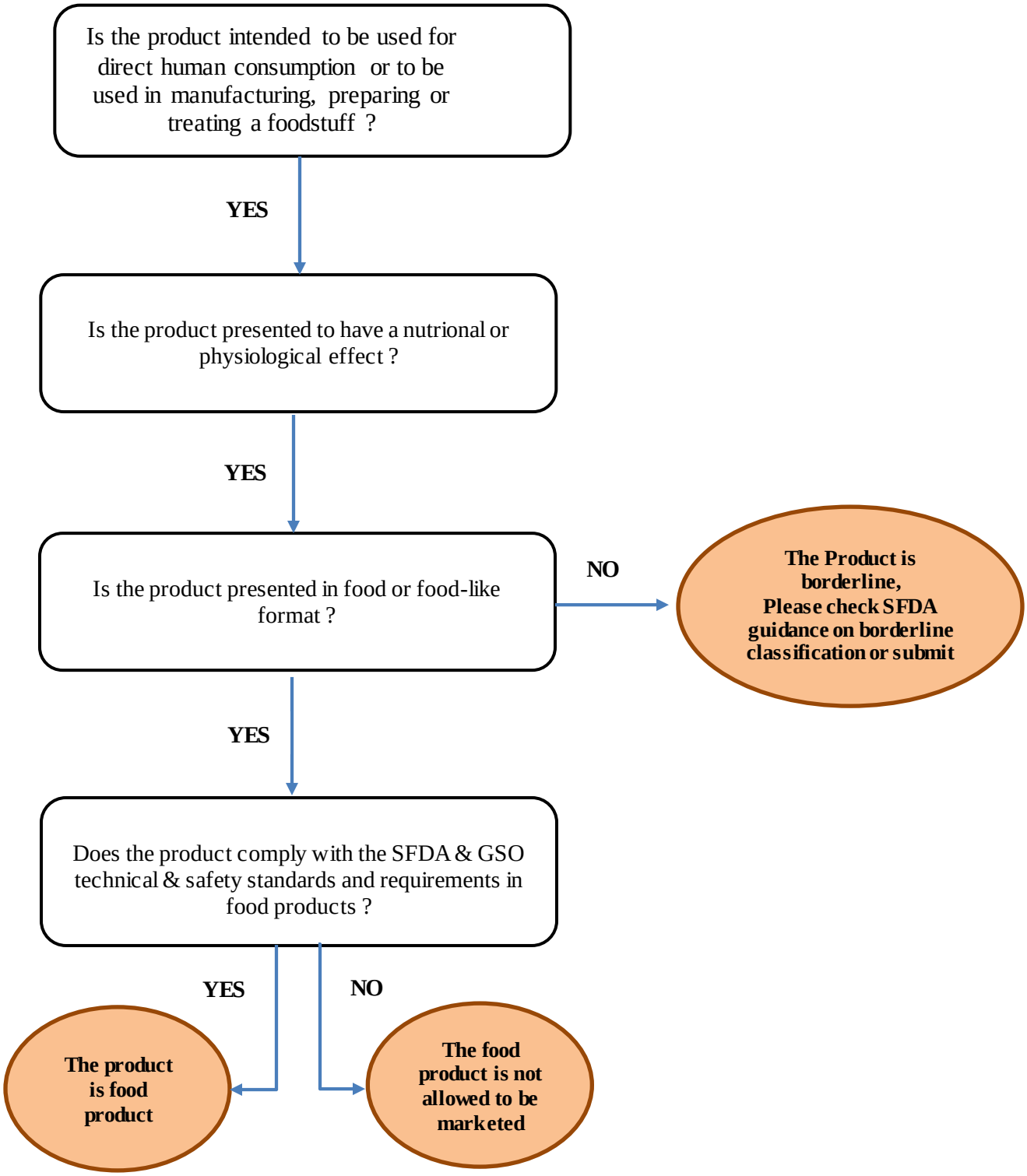
3.30. Coenzyme Q10 that is in concentrations lower than 200 mg/d

3.31. Spirulina Extract that is in concentrations lower than 2400 mg/d, and must adding a warning that the product is not suitable for people with Phenylketonuria

Note:

- For collagen products, please refer to Import requirements published on the SFDA website:https://old.sfda.gov.sa/ar/food/about/administration/mangement_food/Pages/Collagen.aspx
- Food products must comply with the SFDA & Gulf technical regulations and standards such as but not limited to:
  - SFDA.FD 55 Food Supplements
  - SFDA.FD 5002 Infants and Young Children Food
  - SFDA.FD 5003 Infants Formula And Formula For Special Medical Purposes Intended For Infants
  - SFDA.FD 2333 Requirements For Nutrition And Health Claim In The Food
  - SFDA.FD 654 General Requirements For Handling Of Foods For Special Medical Purposes
  - GSO 2397 Foods For Special Dietary Uses – General Requirements For Athlete Food
  - GSO 654 General Requirements for prepackaged foods for special dietary use
  - GSO 2539 Vitamins And Minerals Permitted For Use In Foodstuff
  - GSO 2522 Sports Drinks (Electrolyte Drinks)

General Classification Scheme of Food Products



4. Drug

4.1.Human Pharmaceutical Product

A product would be considered as a drug if it falls within the above-mentioned definition. The definition is including the following products:

4.1.1. One or more vitamins and/or minerals with concentrations above the upper concentration limit of vitamins and minerals. The upper and lower concentrations limits will be calculated according to the product total daily dose. (*Please refer to the General Rules for Products Containing Vitamins And Minerals*)

4.1.2. Products contain any of the following substances:

- Salicylic acid in concentration more than 3% in rinse-off hair products, and more than 2% in other products
- Hydroquinone, (except in artificial nail systems the concentration must be higher than 0.02%)
- Ichthammol and Coal tar
- Tretinoin (Retinoic acid) and its salts
- Glucosamine in pharmaceutical dosage form and in concentrations higher than 1000 mg

4.1.3. Eye preparations that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means

4.1.4. Ear preparations that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means

4.1.5. Peritoneal dialysis solutions

4.1.6. Solution for hemofiltration and haemodiafiltration

4.1.7. Saline and sterile water that are intended for intravenous injection

4.1.8. Parenteral nutrition solution

4.1.9. Injectable drug dosage form

4.1.10. Enema solutions products (rectal solution products)

4.1.11. Therapeutic Radiopharmaceuticals

4.1.12. Medical gases (Oxygen, Helium, Nitrous oxide, Medical air, Carbon dioxide, Nitric oxide+ Nitrogen, Oxygen+ Nitrous oxide and Helium+ Oxygen)

4.1.13. Anti-lice products containing non-listed chemical ingredients such as malathion, permethrin, and pyrethrins

Note:
Please refer to:

- Regulatory framework for drugs approval for various types of drug products and the procedure to submit and authorize the applications, on the following link: https://www.sfda.gov.sa/sites/default/files/2020-09/RegulatoryFrameworkV6-1.pd
- SFDA Circular 4998, for Nasal, Ear, Eye products, Hyaluronic and botulinium toxin injection products, on the following link: https://www.sfda.gov.sa/sites/default/files/2020-10/Generalization-4998.pdf

4.2.Biological Medicinal Products

Based on the above the definition Medicinal products derived from a variety of natural sources or produced by biotechnology methods and other cutting-edge technologies. They include a wide range of products such as the followings:

4.2.1. Blood products and blood derivative products

4.2.2. Vaccines

4.2.3. Allergenics

4.2.4. Analogous

4.2.5. Toxins and Antitoxins

4.2.6. Recombinant protein

4.2.7. Biosimilars

4.2.8. Advanced Therapy Medicinal Products (ATMPs) including:

- Gene therapy medicinal product
- Cell based medicinal product (includes both somatic cell therapy medicinal products and tissue engineered products)

- "Combined ATMP" products contain as an integral part of the product also a medical device

Note:

- Please refer to Guideline on Classification of Advanced Therapy Medicinal Products: https://old.sfda.gov.sa/en/drug/drug_reg/Regulations/ATMPs-classification.pdf

4.3.Veterinary Drugs

4.3.1. Veterinary Medicinal Product

When a substance, part of a substance or a combination of substances associated with a therapeutic (medicinal) property or pharmacological effect.

4.3.2. Insecticides

Veterinary products, which contain substances that kill insects or external parasites, such as pyrethrins, pyrethroids or organophosphate compounds.

4.3.3. Shampoos

A shampoo for animals will be considered medicinal if it contains an insecticide or an ingredient which has a pharmacological effect or is presented as an insecticidal shampoo.

4.3.4. Teat and Udder Products

Products applied internally to teats and udders for the prevention of mastitis.

4.3.5. Herbal Products

Herbal products require a market authorization if they are medicinal by presentation or function. For example, a product containing pyrethrum, pyrethrins or alkaloids, such as digoxin from Digitalis sp., would be considered medicinal by function.

4.3.6. Diagnostic Tools (Testing Kits)

Any substance or combination of substances administered to animals with a view to making a medical diagnosis.

4.4.Herbal and Health Products

4.4.1. Herbal Product

A product would be considered as a medicinal herbal product when it falls within the above mentioned definition. The definition includes the following products:

- Traditional herbal products:

  Traditional medicine (TM) refers to the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures.

- Non-Traditional herbal products (Stand-alone application):

  Non-traditional herbal products must be supported by scientific evidence

Note:

- Please refer to the following:
  - Data Requirements for Herbal & Health Products Submission
  - List of herbs (medicinal plants) allowed
  - List of herbs (medicinal plants) prohibited
- Raw medicinal plants and herbs are not considered herbal products. However, these products shall obtain a clearance. Please refer to Requirments for product clearance
- The number of herbs in the oral dosage form products should not exceed five herbs.
- Homoeopathic preparations are not allowed to be marketed in Saudi Arabia due to the lack of supporting evidence of its safety and efficacy.

4.4.2. Health product:

A product would be considered as a health product subject for registration when it falls within the following definition: Finished, labeled product in pharmaceutical dosage form which may contain one or more of the following ingredients :

4.4.2.1. Amino acid

4.4.2.2. Charcoal

4.4.2.3. Tar

4.4.2.4. One or more vitamins and/or minerals with concentrations equal or below the upper concentration limit provided that none of these vitamins and/or minerals are below the lower concentration limit. The upper and lower concentrations limits will be calculated according to the product total daily dose. (Please refer to the General Rules for Products Containing Vitamins And Minerals)

4.4.2.5. Medicated throat lozenges like resorcinol, Cetylpyridinium and Benzyl Alcohol.

4.4.2.6. Nasal preparations that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means

4.4.2.7. Antiseptic products intended for human use and containing any ingredients of the following:

- Benzalkonium
- Benzethonium
- Chlorhexidine
- Chloroxylenol
- Methylbenzethonium
- Povidone-iodine
- Hydrogen peroxide (H2O2)

4.4.2.8. Alcohol hand sanitizers composed of these ingredients:

- Ethanol 60-80%
- Isopropanol 60-70%

4.4.2.9. A lipid, including an essential fatty acid or phospholipids e.g. omega 3.

4.4.2.10. Throat lozenges which consist only of volatile oils, ascorbic acid (or its salts) and at least menthol with medical claim and at concentration of 5 mg or more. The concentration of the individual ingredients (menthol, eucalyptus oil and Ascorbic acid) must not exceed the maximum value as follows:

- Menthol 5-20 mg
- Eucalyptus oil 0.5-15 mg
- Ascorbic acid 2000 mg

4.4.2.11. Natural enzyme products

4.4.2.12. Sulfur in concentration higher than 2 %

4.4.2.13. Probiotics and prebiotics that are marketed as end products

4.4.2.14. Topical products containing organic acids (Alpha-hydroxy acids (AHAs)) in total concentration of organic acids more than 10%

4.4.2.15. Skin Care Products containing urea in a concentration greater than the recommended by the GSO standards for cosmetic products

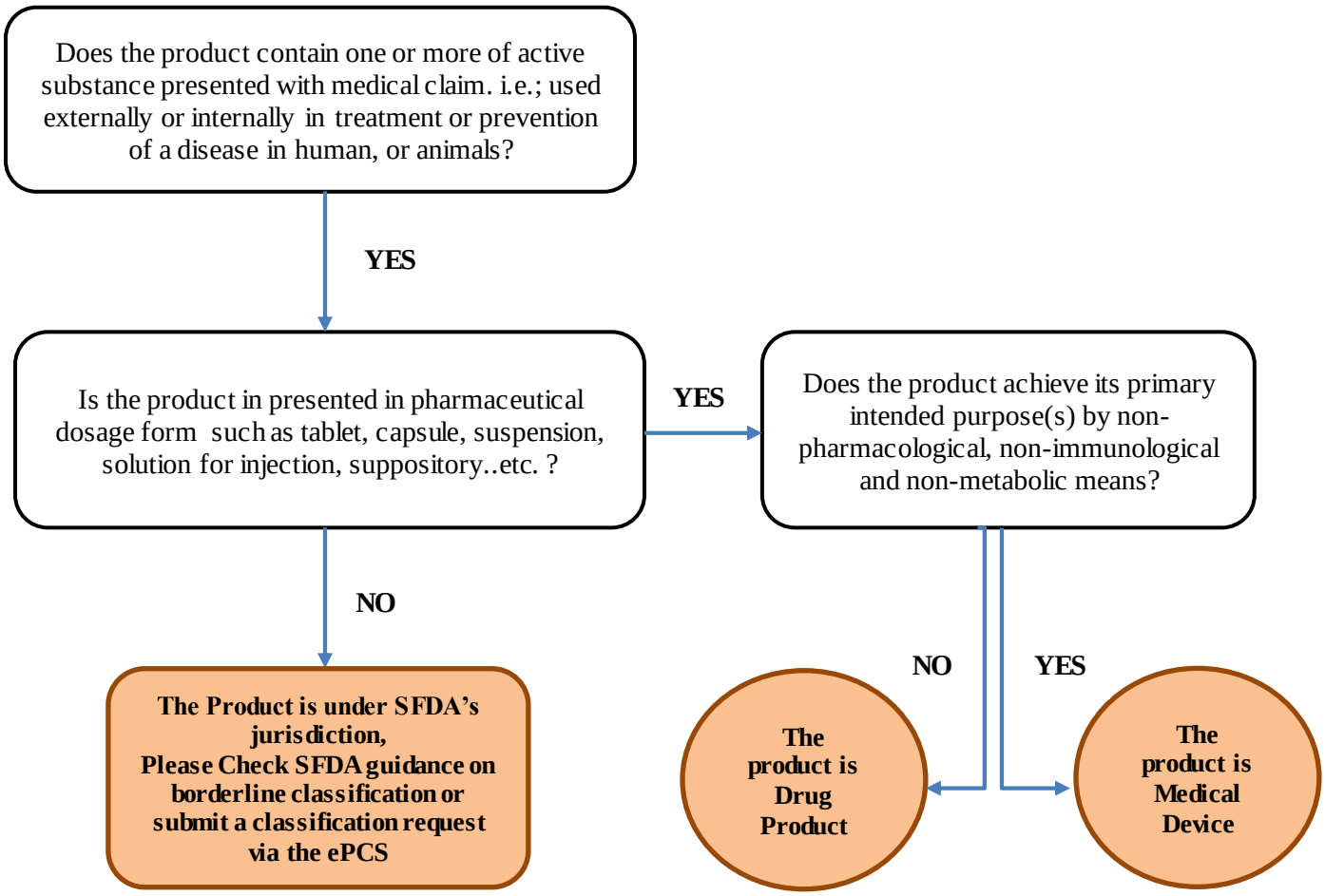
4.4.2.16. Aromatic and medicinal herbal oils that contain one or more of oils that are extracted from medicinal plants that have non nutritional claims and used internally

4.4.2.17. Products containing medicinal herbs that are not in its natural form and have gone through any manufacturing process such as grinding, extraction, packaging or any other manufacturing process

4.4.2.18. Insect repellents in direct contact with human skin

4.4.2.19. Topical patches, creams, ointments and gels containing counter irritant ingredient as an externally applied substance that causes irritation or mild inflammation of the skin for the temporary relieve of pain in muscles or joints by reducing inflammation in deeper adjacent structur

General Classification Scheme of Drug Products



5. Cosmetic Products

5.1.Classification Criteria of Cosmetic Products:

5.1.1. Site of application and dosage form

The products should be 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. Products that are intended for (internal use) cannot be considered to be cosmetic products, e.g.:

Products that are taken orally (syrup, solution, drink, capsules, tablet…etc)

- Products that are taken through the eyes or nose or ear (drops, sprayer...etc)
- Products intended for injection (IV, IM, IS…etc)
- Products that are taken through the anal or vagina (Enema, supposotiry, solution, tab, capsules… etc)

5.1.2. Ingredients

Cosmetic products should not contain any medicinal or therapeutic substances. Also, the cosmetic products shall comply with the COSMETIC PRODUCTS SAFETY REQUIREMENTS SFDA.CO/GSO 1943:2016 and circulars issued by SFDA.

5.1.3. Product main function and claim

The product should be applied to the external parts of human body with a view mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.

Cosmetic products should not contain medicinal or therapeutic claims, and they should not have a significant physiological effect.

5.1.4. Product presentation

The product should not be presented as treating or preventing disease in human beings. The following features of the product should be taken into account:

- Product claims and the context in which the claims are made
- Labeling and packaging/packaging inserts (including graphics)
- Promotional literature, including testimonials and literature issued by third parties on

behalf of the supplier

- Advertisements
- The product form and the way it is to be used e.g. capsule, tablet, injection etc

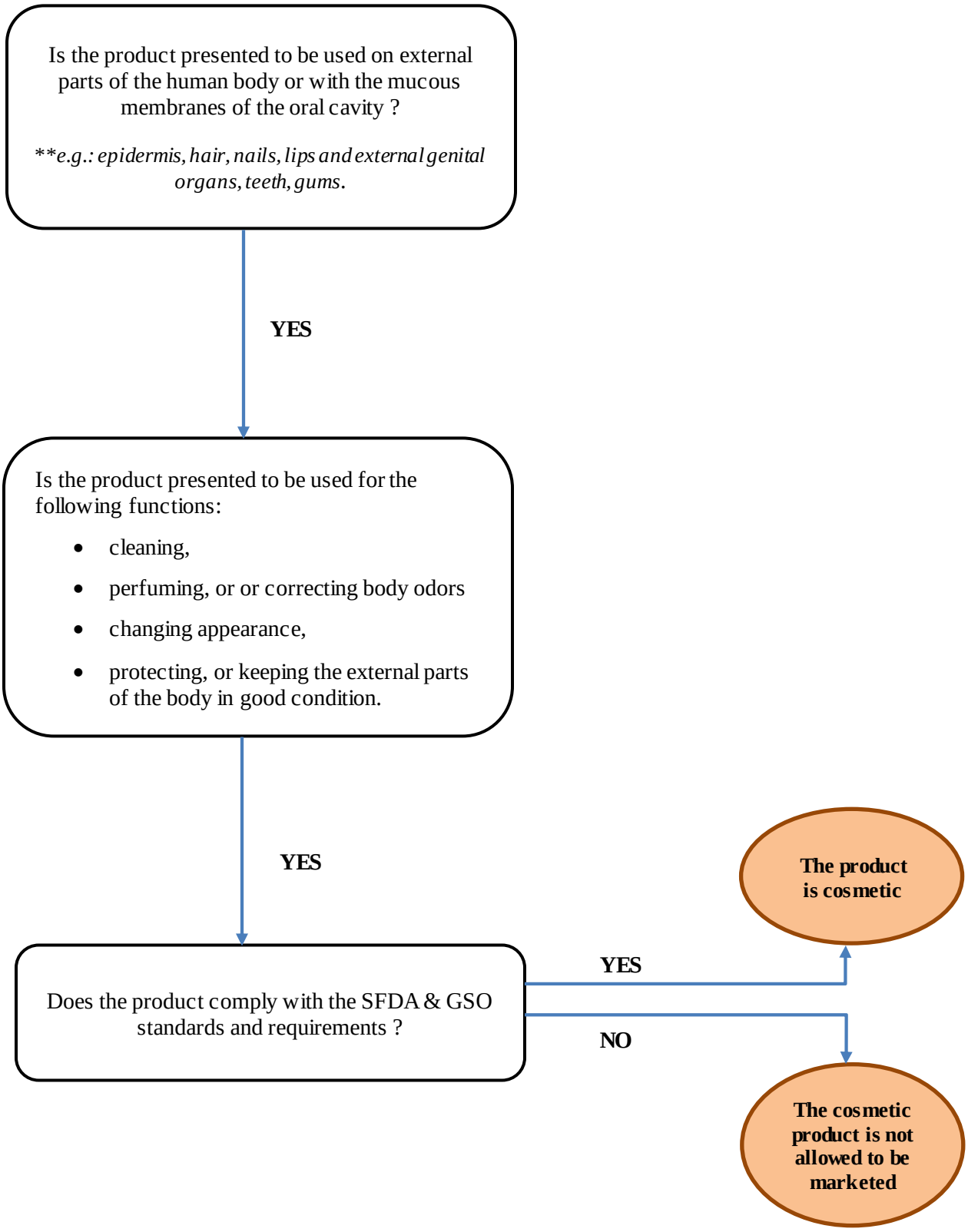
Particular target of the marketing information e.g. specific population groups with, or particularly vulnerable to, specific diseases of adverse conditions.

Note:

All cosmetic products must comply with the following:

- Safety Requirements of Cosmetics and Personal Care Products SFDA.CO/GSO 1943, in addition to the specific product standard (if any), which can be obtained through the GSO website: www.GSO.org.sa
- Circulars issued by SFDA
- Any other technical requirements specified by the SFDA
- List of substances which cosmetic products must not contain except subject to the restrictions laid down
- List of Preservatives Allowed in Cosmetic Products
- List of Colourants Allowed in Cosmetic Products
- List of Substances Prohibited in Cosmetic Products
- LIST OF UV FILTERS ALLOWED IN COSMETIC PRODUCTS

General Classification Scheme of Cosmetic Products



5.2.Products category

The following list is a main category of cosmetic products with examples (but non-exclusive):

5.2.1. Skin Products

a) Skin care Products

- Face care products other than facemask, Facemask, Eye contour products, Lip care products, Hand care products, Foot care products, Body care products, External intimate care products, Chemical exfoliation products, Mechanical exfoliation products, Skin lightening products

b) Skin cleansing products

- Soap products, Bath / shower products, Make-up remover products, External Intimate hygiene products, and other skin cleansing products

c) Body hair removal product

- Chemical depilatories, Physical epilation products, other body hair removal products

d) Body hair bleaching product

e) Correction of body odor and/or perspiration

- Products with antiperspirant activity, Products without antiperspirant activity

f) Shaving and pre- / after- shaving products

g) Make-up products

- Foundation, Concealer, Other face make-up products, Mascara, Eye shadow, Eye pencil, Eyeliner, Other eye make-up products, Lip stick, Lipstick sealer, Other lip make-up products, Body or face paint, including "carnival make-up", Other make-up products

h) Perfumes:

- Hydroalcoholic perfumes, Non hydroalcoholic perfumes

i) Sun and self-tanning products

- Before and after sun products, Sun protection products, Self-tanning products, other sun and self-tanning products

j) Other skin products

5.2.2. Hair and Scalp Products

a) Hair and scalp care and cleansing products:

- Shampoo, Hair conditioner, Scalp and hair roots care products, Antidandruff products, Anti-hair loss products, Other hair and scalp care and cleansing products

b) Hair colouring products:

- Oxidative hair colour products, Non-oxidative hair colour products, Hair bleaching and dye remover products, other hair colouring products

c) Hair styling products:

- Products for temporary hair styling, Permanent wave products, Hair relaxer / straightener products, other hair styling products

d) Hair sun protection products, other hair and scalp products

5.2.3. Nail and cuticle products

a) Nail varnish and remover products:

- Nail varnish / Nail make-up, Nail varnish remover, Nail varnish thinner, Nail bleach, other nail varnish and remover products

b) Nail care products/ products with protection layer for nail

c) Nail glue remover products

d) Other nail and cuticle products:

- Cuticle softener, Nail sculpting products, other nail and cuticle products

5.2.4. Oral hygiene products

a) Tooth care products

- Toothpaste, Tooth cleansing powder / salt, other tooth care products,

Toothpaste products contain one of the following ingredients in a concentration as recommended by the GSO standards for cosmetic products:

- Triclosan
- Chlorhexidine
- Cetylpyridinium
- Cetrimide

b) Mouth wash / breathe spray:

- Mouthwash, Breath spray, other mouthwash / breath spray products

c) Tooth whiteners

d) Other oral hygiene products

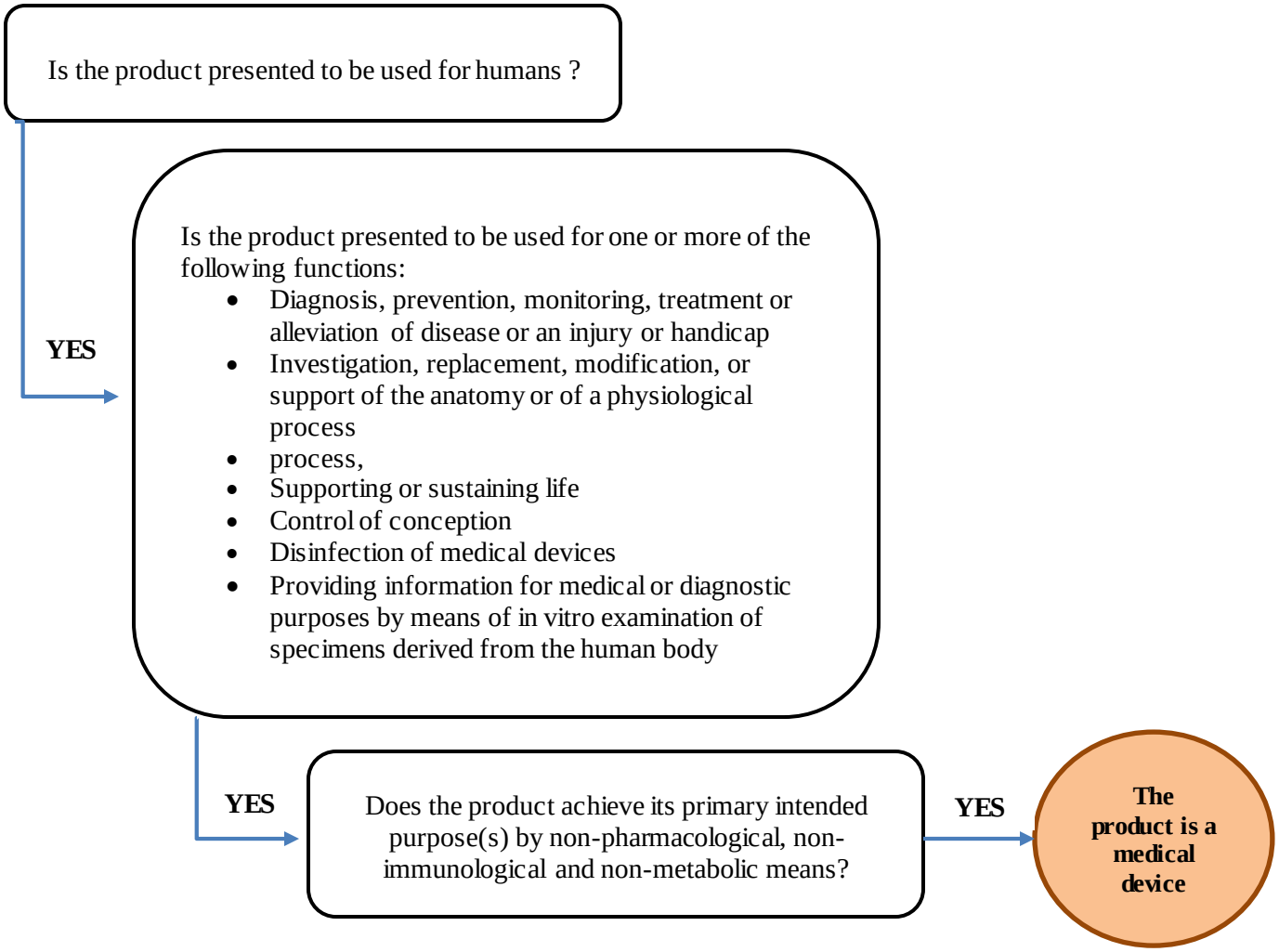
6. Medical Device

The medical device definition states that Medical device "means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article . . .". The SFDA's interpretation is that "similar or related article" under this definition should mean any article in any form. However, "similar or related articles" may be classified as devices as long as they also meet the conditions stipulated in point A and B of the medical device definition.

Note:

- Please refer to MDS-G5 (Guidance on Requirements for Medical Devices Listing and Marketing Authorization)

General Classification Scheme of Medical Device



6.1. In-Vitro Diagnostic medical devices (IVDs):

Products would be considered as IVD if they meet the IVD definition and are intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Examples:

- Reagents used for clinical diagnostic
- Blood glucose meters and strips
- Blood collection tubes, urine sample containers are considered as IVD
- General-purpose laboratory equipment labeled or promoted for a specific medical use
- Densitometry analyzer IVD
- Self-pregnancy test
- The calibrators and control materials used to verify the performance of the analyzers

Note:

- When lancet and pen come in the same kit with blood glucose meter, then the whole kit is considered as medical IVD.

6.2. Laboratory products for non-medical purposes:

a. The labeling of General Laboratory Use (GLU) products shall indicate that the device is For General laboratory Use and Not for medical use or for use in diagnostic procedures. Example:

- Centrifuge
- Scales
- Balances
- Incubators that are not intended to cultivate microorganisms or for the purpose of diagnosis of disease
- Drying oven
- Autoclave for laboratory use
- Multipurpose tubes
- Pipettes

- Mixers
- Shakers

b. Equipment or instrument for detection, reading of non-clinical samples, e.g. pathological agents in the environment, are not IVDs neither general laboratory use. Therefore, they are not regulated by the SFDA

c. Devices for detection of agents of biological or chemical warfare in the environment are not IVD because they do not have a medical purpose

d. Devices for non-medical purposes, even if these devices are used for in-vitro examination of specimens derived from the human body, for example paternity tests or tests for detecting drugs of abuse/alcohol, are not IVD's. therefore, they are not regulated by the SFDA

e. All kits such as reagents, standards, calibrators, indicators …etc, which are used for non-clinical / non-medical purposes are not considered IVD medical devices. However, these kits shall obtain a Medical Device Importation License (MDIL) as non-medical IVD, examples could include but are not limited to the following:

- Reagents used for food and water testing
- Limulus Amebocyte Lysate (LAL) tests for the detection of of endotoxins in injectable pharmaceuticals, biological products and medical devices
- Distillation machines used in the medical field / applications only
- International quality and efficiency samples for clinical/medical labs

6.3. Accessories of IVD medical devices:

The accessories are treated like IVDs in terms of the applicable regulations. They are intended specifically by their manufacturer to:

- Be used together with an IVD medical device to enable that device to be used in accordance with its intended use as an IVD medical device
- Or to augment or extend the capabilities of that device in fulfilment of its intended use as an IVD medical device

Examples:

- A cleaning solution specifically intended by its manufacturer to be used with a

defined automated IVD instrument

- General media such as saline for running instruments

6.4. Chemicals used with/as medical devices:

Some chemical substances and mixtures which are used in its final form in some medical device application require Medical Device Importation License.

Example:

- Chemical substances and mixtures used in fabrication of prosthesis
- Calibration gases and chemicals for medical devices
- Chemical substances and mixtures used to sterilize medical devices
- Gases used to operate medical devcies

Note:

- Chemicals which fall into the above category shall obtain a Medical Device Importation License. However, if the definition of a medical device or an accessory applies, the product must comply with the relevant Medical Device Interim regulations

6.5. In Vitro Fertilization (IVF) and Assisted Reproduction Technologies (ART) products:

Because IVF procedure and product is intended to modify and support a physiological process, they are considered medical devices under the Medical Device Interim Regulation.

Examples of products, which could be qualified as medical devices:

- IVF workstations
- Pipettes or syringes
- Washing, separating, sperm immobilizing, cryoprotecting solutions
- Devices manufactured utilizing animal tissues or derivatives rendered non- viable
- Devices incorporating, as an integral part, a human blood derivative or a medicinal product is liable to act on the human body with action ancillary to that of the devices
- Media intended for use in the IVF process to support the growth storage of the

embryo

6.6. Topical Products:

6.6.1. Wound Management products:

If a wound management product acts physically and does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, it is considered a Medical Device.

Examples of medical devices:

- Non-medicated dressing used as a physical barrier, for compression or for absorption of exudates such as Hydrogel dressings and Alginate dressing
- Devices principally intended to manage the micro-environment of a wound such as honey wound dressing gel
- Wound dressing with antimicrobial substance such as silver to protect the dressing and reduce odor
- Absorbable hemostatic dressings
- Silicone sheets or gel for scars
- Topical patches, creams, ointments and gels that externally applied for the purpose of temporary relieve of pain and irritations

6.7. Radiation Emitting Device/products:

Any device or component of device or accessory to a device, which produces and emits radiation for the purpose of diagnosis, treatment or alleviation of disease, an injury is considered a medical device.

Examples:

- Imaging Products (X-ray, CT, MRI, US, and Nuclear imaging products)
- Diagnostic Radioactive materials
- Digital imaging/x-ray film cassette

Note:
- In-vivo dosimeter to record dose received by a patient during a radiotherapy procedure is a medical device.

6.8. General hygiene products:

General hygiene products are not considered medical devices, as the medical definition does not apply. Moreover, some of these products may achieve its intended purpose through chemical action on the human body.

Examples of non-medical devices:

- Baby nappies
- Feminine hygiene products (sanitary pads)
- General hand cleansing wipes
- General use disinfectants / cleaners for environment, rooms, surfaces
- Dental disclosing solution/tablets
- Insect repellent

However, similar products may be regulated as medical devices, if there is a specific medical purpose.

Examples of medical device:

- Sanitary pads claiming pain relief by physical means
- Adult nappies
- Nibble shields to protect or relieve sore, damaged or cracked nipples or to be which is used to cover and protect the nipple of a nursing mother
- Electrical and manual Breast pumps
- Surgical Razors and clippers
- Reusable/ single use Patient Bedding set
- Disinfectants claiming prevention of disease
- Sitz bath
- Anti-lice products containing natural source oils or ingredients

6.9. Assistive/supportive products:

Assistive and products/devices are regulated as medical devices if they are intended for alleviation of or compensation for an injury or handicap or support of the anatomy of human beings.

Examples of medical device:

- Wheelchairs
- Patient's beds
- Hearing aids
- Walking crutches
- Patient hoists
- Commode chairs
- Abdominal/breast/perineal binders
- Orthoses

However, products for daily use by everyone are not to be considered as medical device

Examples of non-medical devices:

- Portable ramps

6.10. Devices/products for medical personal protective equipment:

If the product is used in a medical field such as operating room with a view to protect the health and safety of the patient, it is considered a medical device. Where a product is intended to protect the user then it falls outside the scope of medical device interim regulation.

Examples non-medical device:

- Non-medical protective gloves
- Dust Mask
- Gum shields for boxers
- Air Purifying Dust/Particulate Respirators

These types of products should not contain any therapeutic (including preventive) claims.

However, if such claims are present or implied, the product is considered to be medical device.

Examples for medical devices:

- Surgical and examination gloves
- Medical face masks
- Surgical apron
- Sharp containers
- Surgical apparel which includes surgical caps, hoods, masks, gowns, drapes, operating room shoes and shoe covers, and isolation masks and gowns

6.11. General health products:

Products for sport or leisure purposes which are used to maintain a healthy status are not considered to be medical devices unless there is intended medical purpose like treatment or diagnosis of pain or injury or monitoring of disease.

Examples for sport products that are not considered medical devices:

- Fitness equipment in general
- Manual massager with no medical purposes
- Watches/activity trackers with/without a heart rate monitor

Examples of medical devices:

- Heat/cold pads for pain relief
- Bandages
- Electrical nerve stimulator for pain relief
- Body Composition analyzer
- Heating and chilling units for packs

- Devices for rehabilitation

Note:

- Blood pressure monitors are considered to be medical devices regardless of where they are used.
- Smartwatch is considered as a medical device when it has diagnosing features.

6.12. Educational and Research Use Only (RUO) products/devices:

6.12.1. Medical devices for research/educational use:

Medical Products/devices which fall into this category shall obtain a Medical Device Importation License which are based on a purchasing order and a attestation letter from the end user.

6.12.2. Kits for research/educational use:

Kits which fall into this category shall obtain a Medical Device Importation License.

6.12.3. Devices labeled as for Research Use Only "RUO":

RUO devices must have no intended medical purposes and be labeled "For research Use Only" to avoid their potential misuse by institutions or laboratories. Such devices are not considered Medical Devices. However, they shall obtain a Medical Device Importation License. This type of product may target the local market and a purchasing order and an attestation letter from a buyer is not required.

Examples:

- RUO products used for Basic Research in research centers
- RUO products used in Pharmaceutical Research

Note:

- All RUO products/devices shall obtain a Medical Device Importation License (MDIL).

6.12.4. Educational Devices:

Devices for educational and training purposes are not regulated as medical devices:

Examples:

- Mock-ups
- Patient simulators

6.12.5. Demo Medical Devices:

If a device is intended for presentation or demonstration proposes, it shall be labeled "for presentation or demonstration purposes only". Medical Device Importation License is required for this type of devices.

6.13. Sterilization and disinfection:

Classification of disinfectants is based on the intended purpose of the product. Any article intended to be used for disinfection of medical devices is considered to be a medical device. A disinfectant is not considered an accessory to the medical device because it is explicitly stated in the definition of medical device and, therefore, is a standalone medical device. However, a disinfectant that is specifically intended for the disinfection of a specific medical device is considered an accessory to this device.

Example of medical devices:

- Ethylene oxide sterilizer
- Detergents for sterilization of medical devices

Disinfectants for dental water line and the fluid pathways of haemodialysis machine

- Denture disinfecting products
- Medical Washers

Note1:

- A pre-sterilization device to clean instruments before being sterilized is considered a medical device. For example, Ultrasonic cleaning unit.

Note2:

- Accessories of medical device disinfectants falls under the scope of Medical Device interim regulations

  Examples of sterilization accessories:

  - Sterilization packaging.
  - Physical/chemical/enzymatic Sterilization process indicator.
  - Instrument tray
- However, general disinfectants intended for general use for rooms, hard surfaces are not considered medical devices. Claims corresponding to these devices should be clearly distinguished from those for a medical device status.

6.14. Healthcare facility products and adaptations:

Not all devices/ equipment, which are used in the health care facility, are medical devices. As these devices do not meet the medical device definition.

Examples of non- medical devices:

- Medical gas pipeline system (excluding system with pressure gauges and regulators)
- Medication refrigerators
- Bedside cabinets
- Overbed tables
- Trolleys for general use (Crash/Emergency trolley is a medical device)
- Mayo Stand
- Air purifiers / Air decontamination units / Mobile air decontamination units
- Gallipots
- Drug storage cabinet

- Hospital linen hampers
- Mortuary fridge

However, some devices are considered medical

Example of medical devices:

- Examination/treatment chair
- Surgical lights as these devices are used to effectively illuminate the field or the patient
- Patient's beds
- Devices intended for temporary storage and transport of organs for transplantation (i.e. containers, bags and similar products)
- Devices intended for long term storage of biological substances and tissues such as corneas, sperm, human embryos, etc. (i.e. containers, bags and similar products)
- Fridges specifically intended for storing blood , tissues etc
- Devices intended to be used for a temporary containment or storage function, e.g. cups and spoons specifically intended for administering medicines

6.15. Dental devices:

Dental devices, which used for treatment of patient, are considered Medical Devices.

Examples:

- Toothbrush (Manual and Powered)
- Dental impression materials and (mixer/syringe /trays).
- Dental restorative materials (composites /glass ionomer …)
- Restorations and base metal alloys
- Implant system
- Amalgamator
- Articulator and facebow
- Dental units

- Scaler
- Pulp tester
- Rubber dam and accessories
- Orthodontic appliance and accessories
- Dentistry products with aluminum chloride used in hemostasis.
- A 5% sodium fluoride desensitizing agent which is administered by a dental professional
- Dental operating light
- Tooth whiteners products containing more than 6% Hydrogen Peroxide

Example of non-medical products:

- Dental casting furnace
- Dental laboratory drilling system hand piece/motor
- Dental laboratory burs

6.16. Devices registered as Medical Devices without an intended medical purpose:

There are some devices which fall under the scope of the Medical Device Interim Regulation (MDIR). These devices are covered below and shall also be classified using the classification rules for medical devices.

6.16.1. Contact lenses or other items intended to be introduced into or onto the eye.

- For Example: Non-prescription colored contact lenses

6.16.2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.

- For Example: Solid body contour modifying implant (e.g. Clavicle or collarbone piercing)

6.16.3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.

- For Example: Dermal fillers

Note:

- Dermal fillers containing hyaluronic acid are considered as medical devices

6.16.4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

- For Example: Body sculpting equipment

High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.

- For Example: Intense pulsed light (IPL) machines for body hair removal

6.16.5. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

- For Example: Transcranial (no surgically invasive) stimulation

6.17. Ophthalmic products:

6.17.1. Sunglasses and spectacle frames:

Spectacle lenses which are used to attenuate rays of light by absorption, reflection, or polarization to protect the eyes from light are considered medical devices.

6.17.2. Eye drops:

- Eye drops intended for the alleviation dryness or discomfort caused by environmental factors in non-pharmacological, non-immunological and/or non-metabolic means

- Balanced Salt Solution(BSS)

BSS intended for eye irrigation during surgical procedure is considered a medical device

6.17.3. Contact lenses and their care products:

Non-corrective lenses, coloured or not are considered to be medical devices.

Examples:

- UV blocking contact lenses to alleviate photophobia
- Contact lenses for therapeutic use as a bandage

Note:

- Contact lenses for cosmetic purposes which have no medical claims must comply with the Medical Device Interim regulation. See 5.16
- Products specifically intended to be used for disinfecting, cleaning, rinsing or, hydrating contact lenses are medical devices.

6.18. Nasal and ear saline preparations:

Nasal and ear saline preparations are considered medical devices

6.19. Lubricants, moisturizers and Gels

6.19.1. Sexual Lubricant:

A non-medicated substance intended to be applied to the penis and vagina for lubrication during sexual intercourse. It is considered a medical device.

6.19.2. Coupling gel:

A medium designed to be applied between an analytical device (e.g., ultrasound transducer) and the patient, allowing signals to pass through the skin during an examination. This type of product is considered a medical device

6.19.3. Body orifice gel:

A substance intended to facilitate entry of a device into a body orifice in the body whether it is a natural opening or any permanent artificial opening. It is considered a Medical Device.

Example:

- Products containing lactic acid for changing vaginal PH

6.20. Contraception devices:

A contraceptive product which acts as by physical means and is intended to control birth is considered a medical device.

Examples:

- Condoms with/without spermicide
- Condom with desensitizing agent such as benzocaine
- Contraceptive diaphragms
- Intrauterine device IUD /with Copper

However, if a product has pharmacological, metabolic or immunological actions. Then, the product is considered medicinal product.

Example of medicinal products:

- Intrauterine device with progestin

6.21. Devices for blood and organ products

- Blood bags (including those containing or coated with an anticoagulant) are considered to be medical device
- Kidney donor-organ preservation/transport perfusion set is considered a medical device
- Hemodialysis Solutions (please refere to point 4.1.4 and 4.15)
- Organ preservation solutions

Note:

Minimally manipulated biological products intended for human applications, must obtain a Medical Device Importation License. Examples of these products:

- Bone ligaments
- Tendons, fascia
- Cartilage
- Ocular tissues (corneas and sclera)
- Skin
- Vascular grafts (veins and arteries except preserved umbilical cord veins)
- Pericardium, amniotic membrane (when used alone without added cells for ocular repair)
- Heart valve allografts.
- Note the following are not considered minimally manipulated biological products:
  - Vascularized organs (liver, kidney, lung, heart….etc.)
  - Major manipulation (e.g. advanced therapeutic drug, gene therapy, tissues engineering therapy)
  - Biologic products imported for research purposes.
- Note that medical devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are required to obtain Medical Device Marketing Authorization.

6.22. Cupping Devices:

Devices used to perform cupping include suction cups and suction pump are considered to be medical device.

Examples of Cupping Devices:

- Suction cup
- Suction pump
- Twist rotary
- Rubber bulb suction

Note:

- Please refer to SFDA.MD 0001/2017 (Safe Use and Handling of Cupping Devices and their Applications)

6.23. Irrigation solutions:

Irrigation solutions intended for mechanical rinsing are considered to be medical devices unless such solutions contain ingredients that have an antimicrobial action on the body such as chlorhexidine and iodine. In this case, such products are regulated by the drug sector.

6.24. Raw materials and components:

Raw materials, component parts or semi-finished products that requires further manufacturing process are not considered medical devices. However, these products shall obtain a Medical Device Importation License

7. Tobacco

It includes the following product types:

- Cigarettes
- Cigars and Tuscan cigars
- Sijaritus
- Almeassel tobacco

- Hand-rolling tobacco and A mixture of tobacco pipe
- E-Liquids and Heated Tobacco Products which are used by Electronic Nicotine Delivery Systems (ENDS)
- Non-nicotine e-liquids which are used by electronic smoking device, and does not contain any medical ingredients or medical claims
- Non-smoked tobacco such as (Timpak, shamma, swika etc.) is prohibited.

Note:

Tobacco products must comply with the SFDA and Gulf technical regulations and standards such as but not limited to:

- SFDA FD 5005: E-Liquids and Heated Tobacco in Electronic Systems for Smoking
- GSO 597: Cigarettes
- GSO 2047: Tuscan cigars and cigarettes
- GSO 2051: Tobacco and its products- Sijaritus
- GSO 1415: Almeassel tobacco
- GSO 1749: Fruit flavored Almeassel tobacco
- GSO 2050: A mixture for tobacco pipe

8. Animal Feed and Public Health Pesticides

8.1. Animal Feed includes the following types:

8.1.1 Feed materials

Is a product of vegetable or animal origin, the main purpose of which is to meet the nutritional needs of animals and which is used for oral feeding, in their natural state, fresh or preserved. Such as:

- Cereal grains and their derivatives,
- Forages and roughage
- Oil seeds, oil fruits and their derivatives,

- Other seeds and fruits and their derivatives
- Legume seeds and their derivatives,
- Tubers, roots
- Milk and milk-based products,
- Fish, other marine animals and their products,
- Minerals,
- Land animal products and their derivatives

8.1.2. Feed additives

Are substances, micro-organisms or preparations that are intentionally added to feed for technological purposes, to improve its taste, to increase its nutritional value, or to improve the animal's performance, whether these ingredients contain nutritional value or not. Products listed in the below table are just an example:

Technological feed additives	Sensory feed additives	Nutritional feed additives	Zootechnical feed additives
Digestibility enhancer	Vitamins	Colorant	Acidity regulators
Gut flora	Minerals	Flavors	Silage additive
Substance for environment	Amino acids		Antioxidant
Enzyme	Urea's		Gelling agent

8.1.3. Premixture:

Are Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, and is intended for incorporation in compound feedingstuffs, feed materials or water and not meant for direct feeding to animals.

8.1.4. Compound feed:

A mixture of at least two feed materials, whether or not containing feed additives.

8.2. Public Health Pesticides

Note:

- Please refer to the SFDA List of Public Health Pesticides.

9. Not Under SFDA's Jurisdiction (NSFDA)

As the main purpose of SFDA is to ensure the safety, quality and efficacy of products under Drug, Food, Cosmetic, and Medical Device regulation, there are some products may inapropriatly overlap with these jurisdictions, and are not considered as borderline products as well. These products are fall outside the SFDA' s responsibility, and may need to be authorized under control of other national regylatory framewoks.

The followings products are the most common examples:

- Hair wigs and eyelashes with no medical claim
- Electrical devices with no medical claim
- Synthetic nails with no medical claim
- Patient ID bracelet/band
- Personel protective non-medical masks and gloves such as :
    - Community masks made of cloth, other textiles, or other materials such as paper
    - Gloves intedned for use in food industry
    - Household cleaning gloves
- Bees Feed
- Surface and environmental disinfectanats without medical claims such as copper film for disinfectant, ultraviolet sterilization for genral purpose, swimming pool disinfectant ..etc.
- Teats (**Except for** Single Use Teats used in hospital environment on neonate to administer medications and special nutrition are regulated as Medical Devices.)

Note:

- For walk-through disinfectant gates, please refere to https://www.sfda.gov.sa/sites/default/files/inline-files/WALK-THROUGH-DISINFECTION-GATE.pdf

10. Borderline Products

Note:

- Please refer to SFDA Guidance for Borderline Products Classification:

  https://ideasbank.sfda.gov.sa/UploadedFiles/b0cddc96-3c0f-47e5-b16a-f90caf1221e7_GuidanceBorderlineProductsClassification.pdf

Products which are difficult to determine whether they are considered as drugs, medical device, herbal or health products are called borderline products.

There are different categories of borderline products, and it may fall generally into the following:

- Food products, especially dietary supplement.
- Cosmetic product
- Health products
- Herbal products
- Drug
- Medical device

The following criteria may be taken into consideration during classification decision-making process:

- Product ingredients and format
- The claim about the product
- Public perception and history of use
- Products representation to the consumers

- The mode and mechanism of action
- Similar classification decisions in SFDA
- Classification schemes of other regulatory authorities

11. Combination product

Note:

- Please refer to SFDA Guidance for Combination Products Classification:

  https://sfda.gov.sa/sites/default/files/2020-10/FINAL_for_implementation.pdf

In order to decide whether a product is regulated as a medical device or a medicinal product, the following points should be considered:

• The intended purpose of the product taking into account the way the product is presented

• The method by which the intended purpose is achieved.

Products that achieve their intended purpose by pharmacological, immunological or metabolic action in/on the body; shall be regulated by drug Sector

Products that do not achieve their principal intended action in or on the body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means, shall be regulated by medical device sector.

Examples of combination products:

- Pre-filled syringes
- Wound dressing with antimicrobial agent
- Surgical scrub brush with antimicrobial agent
- A Helicobacter pylori breath test kit containing labelled urea
  - Urea is considered a medicinal substance
  - A sample container is considered an IVD
- First aid kits

- Toothbrush co-packeged with a toothpaste

Note:

- For first aid kits, please refer to the Guidance on Criteria of Medical Devices Bundling/Grouping within one MDMA Application
- For registration requirements of toothabrush co-packeged with, please refer to: Toothbrush and toothpaste kits

Still need a classification of your product?

If you still need a classification decision about your product which is not covered in this guidance , please sumbit a a product classification request via the e-PCS (please refer to point 2 of this document e-Product Classification System (PCS) Use Process).

- SFDA is currently discussing the classification of below products, and they will be added to the relevant section of the guidance in the future:
  - Food supplements
  - Human disinfectnats and sanitizers
- However at present, these products are regulated as as per version 5.0 of this guidance in order to avoid any gap for manufacturers

Appendix 1

What is New in The Guidance for Products classification (version 5.0)?

The following table shows statements that added, deleted or replaced to the past version 4.1 Oct 22, 2020:

Section	Current Amendment
1.5 Definitions	**Modified**: • Food Supplement • Pharmaceutical dosage form
3. Food	**Clarified** 3.13 Infant and baby foods such as Cereal-based food, Rusks, High protein food and others 3.14 Foods for special medical purposes such as Nutritionally complete formula, Nutritionally incomplete formula, and Formulas for metabolic "genetic" disorders in patients over 12 months. **Added:** 3.28 Chondroitin sulfate that is in concentrations lower than 900 mg/d 3.29 Para-aminobenzoic acid that is in concentrations lower than 1200 mg/d 3.30 Hyaluronic acid that is in concentrations lower than 150 mg/d 3.31 Coenzyme Q10 that is in concentrations lower than 200 mg/d 3.32 Spirulina Extract that is in concentrations lower than 2400 mg/d, and must adding a warning that the product is not suitable for people with Phenylketonuria

	Added: • Additional SFDA & GSO technical Standards in the Not Box
4.1 Human Pharmaceutical Product	**Clarified**: 4.1.2. Products contain any of the following substances • Salicylic acid in concentration more than 3% in rinse-off hair products, and more than 2% in other products • Hydroquinone, (except in artificial nail systems the concentration must be higher than 0.02%) 4.1.3. Eye preparations that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means 4.1.4. Ear preparations that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means **Added** • Note box: SFDA circular 4998 on Nasal, Ear, Eye preparations, and injection products
4.2. Biological Medicinal Products	**Added** 4.2.3. Allergenics 4.2.4. Analogous 4.2.5. Toxins and Antitoxins
4.4.1 Herbal Products	**Added:** • Traditional herbal products • Non- Traditional herbal products

	Added: • Note Box: Lists of herbs (medicinal plants) allowed and prohibited
4.4.2. Health Products	**Re-classified** 4.4.2.12. Electrolyte products, ORS (refer to point 3.12) **Added:** 4.4.2.6. Nasal preparations that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means
5. Cosmetic Products	**Added**: • Note Box: • List of substances which cosmetic products must not contain except subject to the restrictions laid down • List of Preservatives Allowed in Cosmetic Products • List of Colourants Allowed in Cosmetic Products • List of Substances Prohibited in Cosmetic Products • LIST OF UV FILTERS ALLOWED IN COSMETIC PRODUCTS
6. Medical Device	**Added:** 6.4. Chemicals used with/as medical devices: • Gases used to operate medical devices 6.8. General hygiene products • Examples of medical devices: adult nappies 6.21 Devices for blood and organ products • Note Box: • Medical devices manufactured utilising

	tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are required to obtain Medical Device Marketing Authorization.
7. Tobacco	**Added**: • Sijaritus • Note Box: additional SFDA and GSO technical standards
8.1 Animal Feed	**Added**: • Illustrative examples on animal feeds
9. Not Under SFDA's Jurisdiction (NSFDA)	**Newly Added Section:** • Common examples
10. Borderline Products	**Added:** • Note box: SFDA Guidance for Borderline Products Classification
11. Combination Products	**Added:** • Note box: Registration requirements of toothbrush co-packeged with a toothpaste

Appendix. 2

Comments on Products Classification Guidance

Please submit comments to the following E-mail: Classification Feedback			
Proposed Amendment	Item text	Item No.	
			1
			2
			3
			4
			5
			6
			7
			8
			9
			10