PICTORIAL GUIDE TO CLASSIFICATION OF FOOD OR DRUG PRODUCTS

APPENDIX 2

	REGULATED BY FSQD
	REGULATED BY NPRA
	CLASIFICATION OF FDI UNDER FOOD OR DRUG

PRODUCT

DRUG

1. **Product as defined in Regulation 2, CDCR 1948.**
2. **Products containing 100% active ingredient(s) with or without excipient.**
3. **Products containing specific active ingredients, which possess high pharmacological or therapeutic potencies,** (e.g. paracetamol, glucosamine, tranexamic acid, aspirin, substances listed in Poisons Act 1952)
4. Products containing specific active ingredients, which possess dose-related therapeutic potencies such as:
   - Plant sterols/ stanols and esters that are consumed ≥ 3.5g/ day
   - Psyllium husk that are consumed ≥ 3.5g/ day
   - Products containing senna ≥0.5g
5. **Products in pharmaceutical dosage form** such as soft gel, capsule or tablet (that is to be directly swallowed), sublingual, buccal, spray into the mouth, etc.

1. Product containing ingredient(s) from Negative List of FDI
2. Products not containing ingredient(s) from Negative List for FDI and with medicinal/ health claim.
3. Products intended to be used or capable or purported or claimed to be capable for medicinal purpose. (e.g. products used for the health benefit of eyes, body weight control, gastrointestine, brain, etc,)

FOOD

1. 100% food ingredients
2. Food products with or without active ingredients as below;

i. Instant drink products containing sugar and/ or creamer (e.g. premix coffee, tea, chocolate, soy, cereal)

ii. Meat essence products (liquid) (e.g. chicken essence, ostrich essence, duck essence, fish essence, etc.)

iii. Ready to drink products (beverages) without dose instruction in cheer pack/cans/ packet drinks

iv. Cordial products with recommended dilution ratio (e.g. dates cordial, grape cordial)

v. Vinegar products (powder & liquid) (e.g. apple vinegar, dated vinegar, etc)

vi. Honey products (powder & liquid)

3. Isotonic drin products, sport nutrion products and special purpose food products
4. Products in conventional food form e.g. biscuit, cake, confectionery, candy/ sweet, gummy, noodle
5. Products used for cooking and food preparation (e.g. cooking oil (olive oil, coconut oil, sunflower oil), herbs and spices)
6. Herbs and spices in crude form without medicinal/ health claim

Products non containing ingredient(s) from Negative List for FDI and without medicinal/ health claim.

Source: Drug Registration Guidance Document (DRGD), 3rd Edition, 7th Revision January 2024 Food-Drug Interphase (FDI) Products