APPENDIX 1

FOOD - DRUG INTERPHASE (FDI) PRODUCTS

This guide serves to assist in determining if a product is regulated by the National Pharmaceutical Regulatory Agency (NPRA) or by the Food Safety and Quality Division (FSQD) of the Ministry of Health Malaysia.

1. INTRODUCTION

Malaysians are now more health conscious and there is generally greater awareness of the importance of nutrition to overall well-being. In recent years, many consumers also rely on a variety of "dietary supplements" to improve their health. These diverse products are freely available through a myriad of outlets. A variety of products are available in the market, supposedly for the maintenance, prevention and even treatment of chronic diseases. These products may range from foods modified to have special properties or pure forms of vitamins and minerals to extracts of various botanical or animal products.

It is important to monitor and regulate the marketing and sale of these products to protect the interest and health of the consumer. Some of these products are not clearly defined as "food" or "drugs" but are freely marketed. Such products include a variety of so-called health products and have been termed as "food-drug interphase (FDI) products".

In order to better define and regulate the FDI products, both the NPRA and the FSQD, Ministry of Health Malaysia formed the Committee for the Classification of Food-Drug Interphase Products in 2000. The main Terms of Reference of the Committee is to assist both Divisions in classifying, in a consistent manner, any application from the industry not clearly defined either as a food or drug product. The Committee also serves as a platform in strengthening and updating the relevant regulations as well as to provide scientific input on these products.

2. FOOD PRODUCTS REGULATED BY FSQD INCLUDE:

2.1 100% food ingredients

2.2 Food products with or without active ingredients (e.g.: herbs, vitamins, minerals, etc.) such as:

i) Instant drink products containing sugar and 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 dosing instruction in cheer packs/ 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, dates vinegar, etc.)

vi) Honey products (powder & liquid)

2.3 Isotonic drink products, sport nutrition products and special purpose food products

2.4 Products in conventional food form, e.g. biscuit, cake, confectionery, candy/sweet, gummy, noodle

2.5 Products used for cooking and food preparation (e.g. cooking oil (olive oil, coconut oil, sunflower oil), herbs and spices)

2.6 Herbs and spices in crude form without medicinal/ health claim

3. PRODUCTS REGULATED BY NPRA INCLUDE:

3.1 Products containing active ingredient(s) with or without excipient

3.2 Products containing specific active ingredients, which possess high pharmacological or therapeutic potencies. Examples of the ingredients are paracetamol, glucosamine, tranexamic acid, aspirin, and substances listed in Poisons Act 1952

3.3 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

3.4 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.

4. FDI PRODUCTS

Generally, FDI products are products with combination of food ingredients and active ingredients for oral consumption. FDI products are not clearly defined as food or drug. Examples of food ingredients are fruits, vegetables, meat, poultry, milk, cocoa and cereal. Examples of active ingredients are vitamins, minerals, herbs, enzymes, probiotics, prebiotics, amino acids, peptides, coral calcium, fatty acids, collagen, chia seed, astaxanthin, lutein and other ingredients that are not traditionally consumed as food. FDI products may be presented in the form of powder, liquid, semisolid forms such as gel/ jelly, chewable tablet, drops, granule, etc.

4.1 Classification of FDI Products

FDI is **not a product category** and it is important to determine whether the products are regulated as drug (under the NPRA's purview), or as food (under the FSQD's purview) because different regulatory requirements apply. The classification of FDI products are based on criteria, as outlined below:

a) Main criteria

i. Negative List for FDI as listed in Table I: Negative List For FDI:

FDI products containing ingredient(s) from Negative List for FDI shall be regulated by NPRA; or

ii. Medicinal/ health claim refer to the term "medicinal purpose" as stipulated in the Sales of Drug Act 1952, Section 2:

FDI products not containing ingredient(s) from Negative List for FDI and with medicinal/ health claim shall be regulated by NPRA; or

FDI products not containing ingredient(s) from Negative List for FDI and without medicinal/ health claim shall be regulated by FSQD.

iii. Products intended to be used or capable, or purported or claimed to be capable for a medicinal purpose (e.g. products used for the health benefit of eyes, body weight control, gastrointestine, brain, etc.) shall be regulated by NPRA.

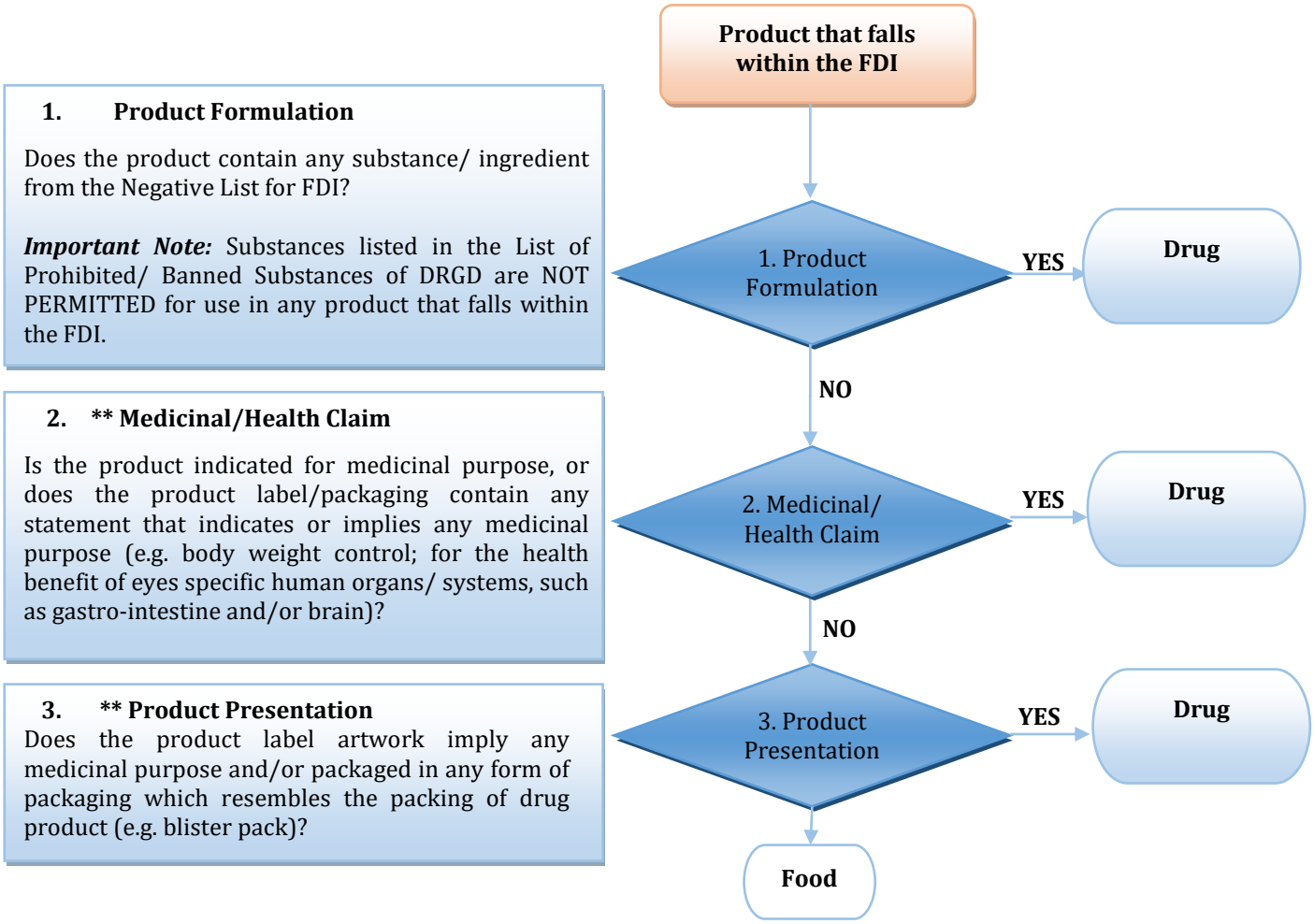
b) Other criteria

When there is greater uncertainty regarding the safety of a FDI product, such product shall be regulated by NPRA. This is to enable closer monitoring of such product to safeguard the health of the consumer.

Reference: *Pekeliling Kriteria Baru Pengkelasan Produk Food-Drug Interphase (FDI)* (7 August 2014) *Bil. (19)dlm.BPFK/PPP/01/03 Jld.3*

CLASSIFICATION FLOWCHART OF FDI UNDER FOOD OR DRUG

- The following flowchart serves only as a guide to help determine the category of the product that falls within the FDI.
- Contact the relevant regulatory agencies for clarification, or seek classification service from NPRA by submitting a classification application should there be doubt or uncertainty pertaining to the category of the product.
- Read the governing legislations and other regulatory requirements and guidelines that apply to the product before using this guide.



Note: ** NPRA reserves the right to use its discretion to make decision if any issue of subjectivity arises.

5. ADDITIONAL NOTES

5.1 Substances listed in the prohibited/ banned ingredient list of the Drug Registration Guidance Document (DRGD) and Schedule Poison shall not be permitted for use in any FDI products.

5.2 Products categorized as a natural product are not allowed to contain creamer.

5.3 Food products are not allowed to be packed in blister pack/ any other form of packaging that resembles the packaging of drug product.

5.4 Any foods or combination of foods that are regulated by FSQD shall not be in pharmaceutical dosage form. Such products are advised to be reformulated into a non-pharmaceutical dosage form.

5.5 Products containing only ingredient(s) such as roselle, jasmine, rose, chamomile, chrysanthemum flower, ginger (rhizome), vanilla(stem), mint leaf, lemon peel and cinnamon bark (with/without C*amelia sinensis*) will be regulated by FSQD.

5.6 Fruit ingredients that are not commonly consumed as food in Malaysia will be considered as active ingredient.

Table I: Negative List for FDI

No.	Ingredient	Common / Other name
1	***Actaea racemosa***	Black Cohosh, Cimicifuga racemosa
2	***Antiaris toxicaria (Pers.) Lesch.***	Bark cloth tree, antiaris, false iroko, false mvule, upas tree
3	***Artemisia Spp. (all species)***	Wormwood, Mugwort
4	***Aspidosperma Quebracho-Blanco Schltdl***	Kebrako, White Quebracho
5	***Atropa Spp. (all species)***	Antropa belladonna (deadly nightshade)
6	***Azadirachta indica***	Nimba, Neem
7	**Bile**	
8	***Brucea javanica, Brucea amarissima***	Sumatrana amarissimus, Java brucea
9	***Bufo gargarizans Cantor, Bufo melanostictus Schneider, Bufo vulgaris Lour***	Toad, Samsu, kodok, kerok
10	***Calotropis Spp. (all species)***	Apple of Sodom, Crown flower
11	***Cannabis Spp. (all species)***	Marijuana, Hemp
12	***Catharanthus Spp. (all species)***	Periwinkle
13	***Chelidonium majus***	Celandine, Great Celandine, Nipplewort
14	***Chondodendron Spp. (all species)***	
15	***Claviceps Spp. (all species)***	Ergot
16	***Colchicum Spp. (all species)***	Autumn crocus, Meadow saffron, Naked lady
17	***Conium maculatum***	Hemlock
18	***Coptis chinensis, Coptis teeta***	Chinese Goldthread
19	***Croton tiglium L.***	Croton
20	***Datura Spp. (all species)***	Jimson weed, Devil's apple, Green Dragon, Zombie's Cucumber, Moon Weed, Trumpet Lily, Stinkweed
21	***Digitalis Spp. (all species)***	

No.	Ingredient	Common / Other name
22	***Dioscorea Hispida***	
23	***Dryobalanops lanceolata Burck***	Borneo camphor, Kapur, Malay Camphor, Sumatra camphor
24	***Dryopteris Spp. (all species)***	Mountain woodfern, Spinulose woodfern, Spreading woodfern, Fancy fern
25	***Euphorbia Spp. (all species)***	Spurge
26	***Fritillaria Spp.***	Fritillary Bulb
27	**Gamma-amino Butyric Acid (GABA)**	
28	***Garcinia Morella Desr.***	Gamboge
29	***Gelsemium semperi virens***	Palaung Thay
30	**Glucosamine**	
31	**Glutathione**	
32	***Gypsum Fibrosum***	
33	**Hyaluronic acid**	
34	***Hyoscyamus Spp. (all species)***	
35	***Hypericum perforatum***	St. John's Wort
36	***Juniperus sabina***	Savin, Savine
37	***Mahonia aquifolium, Mahonia repens, Mahonia nervosa***	Mahonia Aquifolium: Oregon Grape, Mountain Grape, Barberry. Mahonia Repens: Creeping Barberry, Creeping Mahonia, Creeping Oregon-Grape
38	***Melanorrhoea usitata Wall.***	Vanish tree
39	***Monascus purpureus***	Red yeast rice
40	***Mucuna pruriens***	Cowhage, Cowage
41	***Mylabris phalerata, Mylabris cichorii***	Blister beatle, Mylabris
42	**Natto extract**	Fermented soybean extract

No.	Ingredient	Common / Other name
43	***Nerium indicum***	Indian oleander, Exile Tree.
44	***Nerium oleander***	Indian oleander, Exile Tree.
45	**Pearl**	
46	***Phellodendron amurense, Phellodendron chinense***	Amur Cork tree
47	**Placenta**	
48	***Plumbago indica***	Rose-coloured leadwort
49	***Plumbago zeylanica***	White leadwort
50	***Psilocybe cubensis***	Boomers, Gold caps
51	***Rauvolfia Spp. (all species)***	
52	**Resveratrol**	
53	***Sanguinaria canadensis***	Bloodroot, Indian Paint
54	***Scilla sinensis***	
55	***Simmondsia Chinesis***	Jojoba
56	***Sophora tomentosa***	Sea coast Laburnum, Silver Bush
57	***Spigelia marilandica***	Worm grass, Pinkroot
58	***Stichopus Spp.***	Gamat
59	***Strophanthus Spp. (all species)***	Kombe
60	***Strychnos ignatii, Strychnos lucida, Strychnos roberans***	Nux-vomica
61	***Symphytum peregrinum***	Comfrey

Notes:

This list :

- is a compilation by the FDI committee.
- is not meant to be exhaustive and will be reviewed from time to time.
- shall be read in conjunction with the current laws and regulations together with other relevant legislations, where applicable, governing pharmaceutical and natural products for human use in Malaysia.

CLASSIFICATION OF FOOD OR DRUG PRODUCTS

	Regulated by FSQD
	Regulated by NPRA
	Classification of FDI under food or drug

PRODUCT

DRUG

1. **Products as defined in Regulation 2, CDCR 1984.**
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. Products containing ingredient(s) from Negative List For 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 a 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, dates vinegar, etc.)
   vi) Honey products (powder & liquid)
3. **Isotonic drink products, sport nutrition 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 not containing ingredient(s) from Negative List for FDI and without medicinal/ health claim.