



*Biro Pengawalan Farmaseutikal Kebangsaan,
Kementerian Kesihatan Malaysia*



*WHO Collaborating Centre
For Regulatory Control of Pharmaceuticals*



*Member of Pharmaceutical
Inspection Cooperation Scheme*



MS ISO 9002 REG. No : AR 1171

MS ISO 9001:2000 Certified

CLASSIFICATION OF FOOD-DRUG INTERPHASE (FDI) PRODUCT

National Pharmaceutical Control Bureau
Ministry of Health Malaysia
Lot 36, Jalan Universiti
46200 Petaling Jaya
MALAYSIA

Tel : 603-78835400 Fax : 603-79581312

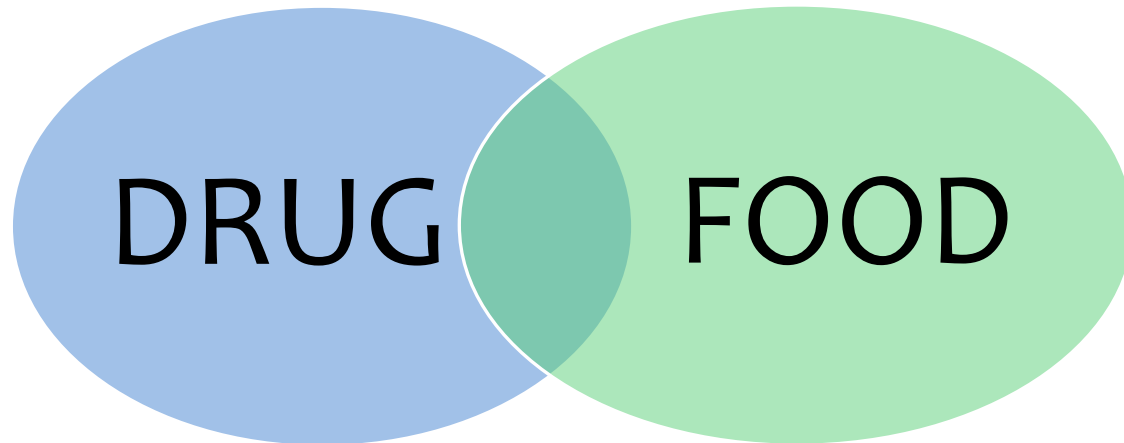
Website : www.bpfk.gov.my

PRESENTATION OUTLINE

- * Introduction: Food, Drug and Food-Drug Interphase
- * Classification of FDI Products
- * Circular
- * Classification Application
- * Summary

INTRODUCTION

Food-Drug Interphase Products (FDI)



ACT & REGULATIONS

Food

FOOD ACT 1983

FOOD – every article manufactured, sold or represented for use as **food or drink** for human consumption or which enters into or is used in the composition, preparation, preservation, of any **food or drink**

Regulated by Food Safety and Quality Division (**FSQD**)

Approval is not required before the product is marketed

Drug

CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984

**

Regulated by National Pharmaceutical Control Bureau (**NPCB**)

Approval is required before the product can be marketed

DEFINITION

PRODUCT

'Product' as defined in the Regulations:

Control of Drugs and Cosmetics 1984

A 'drug' in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a **medical purpose**.

A 'drug' to be used as an ingredient of a preparation for a **medicinal purpose**;

Sale of Drugs Act 1952

'Drug' includes any substance, product or article **intended to be used or capable, or purported or claimed to be capable** of being used on humans or any animal, whether internally or externally for a **medicinal purposes**

FOOD PRODUCTS



**DAIRY PRODUCTS, MILK BASE PRODUCTS,
MALT PRODUCTS**



INSTANT (3 IN 1) DRINK



SOFT DRINKS, CANNED DRINKS, FRUIT JUICES

DRUG

- * Products with conventional drug presentation and use (100 % active ingredient and/or in pharmaceutical dosage form such as capsule, tablet, softgel or sublingual) shall be classified as drug and need to be registered.
- * This category of products shall be regulated by **National Pharmaceutical Control Bureau (NPCB).**



DRUG PRODUCTS



**PRESCRIPTION PRODUCT:
opium, cannabis**



**OTC PRODUCT: cough syrup,
laxative products**



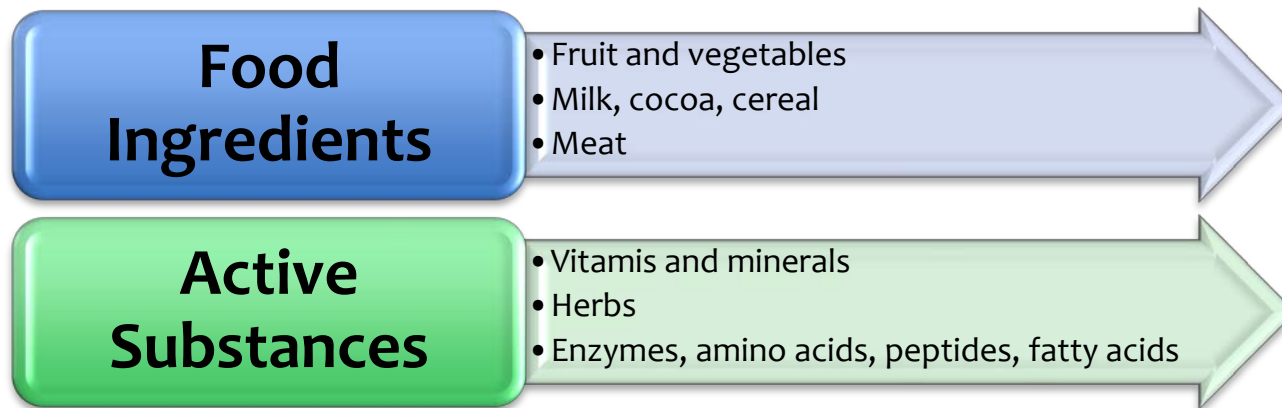
**HEALTH SUPPLEMENT
PRODUCTS**



TRADITIONAL PRODUCTS

FOOD-DRUG INTERPHASE (FDI)

- * FDI Products : Products for **oral** consumption containing a **combination** of food ingredients with active substances



FOOD-DRUG INTERPHASE COMMITTEE

- * FDI Committee- Since 2000
- * To assist both NPCB & FSQD in classifying, in a consistent manner, FDI products which are 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.
- * Classification of FDI product by single authority NPCB
 - For consistency in decision making

FOOD PRODUCTS

- A. Food based products with/without the addition of active ingredients (eg: herbs, vitamins and minerals)
- B. Energy/Isotonic drink, Sports Nutrition and Food for Special Purpose
- C. Conventional Food Forms
 - (Eg: Cake, Chocolate, Sweets, Gummies, Noodles)
- D. Products used for cooking and food preparations
 - (Eg: Olive Oil/Palm Oil/Sunflower Oil, Turmeric)
- E. Herbs and spices in crude form



**Controlled by Food Safety and Quality Division
(FSQD)**

FOOD PRODUCTS

A. Food based products with/without the addition of active ingredients (eg: herbs, vitamins and minerals)



I. Instant drink with sugar and creamer
(Eg: 3 in 1 coffee, Chocolate drink)



II. Essence Product (Liquid)
(Eg: Chicken essence, Fish essence)



III. Ready to drink beverages
(Eg: Canned/Boxed drink)

FOOD PRODUCTS

A. Food based products with/without the addition of active ingredients (eg: herbs, vitamins and minerals)



IV. Cordial
(Eg: Red dates
essence,
Grape
essence)



V. Vinegar
(Liquid)
(Eg: Apple
cider vinegar,
Dates vinegar)



VI. Honey
(Liquid)
(Eg: Pure
honey, Honey
with herbs)

FOOD PRODUCTS

B. Energy/Isotonic drink, Sports Nutrition and Special Purpose Food

SPECIAL PURPOSE FOOD



ENERGY DRINK



SPORTS NUTRITION



FOOD PRODUCTS

C. Conventional Food Forms

- * (Eg: Cake, Chocolate, Sweets, Gummies, Noodles)



FOOD PRODUCTS

- D. Products used for cooking and food preparations
* (Eg: Olive Oil/Palm Oil/Sunflower Oil, Turmeric)



FOOD PRODUCTS

E. Herbs and spices in crude form



FDI PRODUCTS CLASSIFICATION

- * The classification of FDI products are based on criteria, as outlined below:
 - * the presence of ingredient listed in **Negative List For Food** and/or
 - * any **medicinal claims** which fulfill the definition of **medicinal purpose** according to the Sale Of Drugs Act 1952

NEGATIVE LIST FOR FOOD

NEGATIVE LIST FOR FOOD

- Gamat
- Gypsum Fibrosum
- Red Yeast Rice
- Natto extract
- Placenta
- Bile (Hempedu)
- Glucosamine
- Hyaluronic acid
- Glutathione
- Gamma-amino Butyric Acid (GABA)
- Resveratrol
- Pearl

NEGATIVE LIST FOR FOOD

- Actaea
- Artemisia Spp.
- Azadirachta indica
- Brucea javanica, Brucea amarissima
- Bufo gargarizans Cantor, Bufo melanostictus Schneider, Bufo vulgaris Lour
- Chelidonium majus
- Conium maculatum
- Coptis chinensis, Coptis teeta
- Croton tiglium L

NEGATIVE LIST FOR FOOD

- Datura spp
- Digitalis spp. Dryobalanops lanceolata Burck
- Fritillaria spp.
- Gelsemium semperi virens
- Hypericum perforatum
- Mahonia aquifolium, Mahonia repens, Mahonia nervosa
- Melanorrhoea usitata Wall.
- Mucuna pruriens
- Mylabris phalerata, Mylabris cichorii
- Nerium indicum
- Nerium oleander

NEGATIVE LIST FOR FOOD

- Phellodendron amurense, Phellodendron chinense
- Plumbago indica
- Plumbago zeylanica
- Psilocybe cubensis
- Sanguinaria canadensis
- Scilla sinensis
- Sophora tomentosa
- Spigelia marilandica
- Strophanthus spp. (all species)
- Symphytum peregrinum
- Strychnos ignatii,
- Strychnos lucida,
- Strychnos roberans

NEGATIVE LIST FOR FOOD

Notes:

- * This list :
 - * is a compilation by the food-drug interphase (FDI) committee.
 - * is comprehensive and non-exhaustive.
 - * shall/ can be amended 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, which include but not limited to the following:
 - a) Sale of Drugs Act 1952;
 - b) Control of Drugs and Cosmetics Regulations 1984;
 - c) Dangerous Drugs Act 1952;
 - d) Poisons Act 1952;
 - e) Medicines (Advertisement & Sale) Act 1956;
 - f) Patents Act 1983;
 - g) Wildlife Conservation Act 2010 (Laws of Malaysia Act 716); and
 - h) International Trade in Endangered Species Act 2008 (Act 686).
 - i) Food Act 1983 (Act 281) & Regulations

- * The written laws shall take precedence over this guidance document in any event of discrepancy.

HEALTH/MEDICINAL CLAIM

CDCR 1984

- * "product" means—
 - (a) a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a **medicinal purpose**; or
 - (b) a drug to be used as an ingredient of a preparation for a **medicinal purpose**.

Sale of Drugs Act 1952

- * 'Drug' includes any substance, product or article **intended to be used or capable, or purported or claimed to be capable** of being used on humans or any animal, whether internally or externally for a **medicinal purposes**

MEDICINAL PURPOSE

Sale of Drugs Act 1952

- * (a) alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease;
- * (b) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;
- * (c) contraception;
- * (d) inducing anesthesia;
- * (e) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function;
- * (f) controlling body weight;
- * (g) general maintenance or promotion of health or wellbeing;

CIRCULAR

- * A circular regarding this classification guide is available at NPCB's website.

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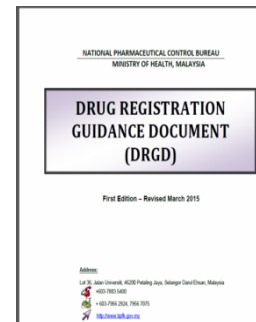
Circulars / Directive

Search Term: FDI Search Reset

Circulars - Regulatory Information

No.	Document Name	Type	Size
1.	PEKELILING KRITERIA BARU PENGKELASAN PRODUK FOOD-DRUG INTERPHASE (FDI)	PDF	2.22 MB
2.	PEKELILING KRITERIA BARU BAGI PENDAFTARAN PRODUK FOOD-DRUG INTERPHASE (FDI)	PDF	0.42 MB
3.	Keperluan Pendaftaran Produk Food-Drug Interface (FDI) Yang Mengandungi Bahan Aktif Red Yeast Rice, Natoto Extract, Placenta, Bile, Glucosamine, Hyaluronic Acid, Glutathione, Gaba dan Resveratrol	PDF	0.11 MB

- * Drug Registration Guidance Document (DRGD)



- * This classification guide is effective starting from **9 JULY 2014**.



Ruj Kami : Bil (19)dlm.BPFK/PPP/01/03 Jld.3
Tarikh : 07 AUG 2014

**SEMUA SYARIKAT BERKENAAN
SEMUA PERSATUAN BERKENAAN (SEPERTI SENARAI EDARAN)**

Tuan/ Puan,

PEKELILING KRITERIA BARU PENGKELASAN PRODUK FOOD-DRUG INTERPHASE (FDI)

Adalah saya merujuk kepada perkara tersebut di atas.

2. Seperti yang tuan/puan sedia maklum, secara umumnya produk FDI merupakan produk dengan formulasi kombinasi bahan makanan dan bahan aktif seperti vitamin, mineral dan herba. Pengelasan produk-produk ini ditentukan berdasarkan konsep pengiraan peratusan bahan aktif dalam formulasi produk (konsep 20:80). Sekiranya kandungan bahan aktif melebihi 20% maka produk tersebut dikategorikan sebagai Ubat dan perlu berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD), Kementerian Kesihatan Malaysia (KKM).

3. Seiring dengan perkembangan inovasi industri makanan di Malaysia, Jawatankuasa FDI dalam Mesyuarat FDI Bil 02/2014 bertarikh 9 Julai 2014 telah mengkaji semula kriteria pengelasan produk FDI dan membuat keputusan berikut:

- 3.1 Pengelasan produk FDI berdasarkan pengiraan peratus bahan aktif (konsep 20:80) digugurkan dan tidak akan digunakan.
- 3.2 Kategori produk **Makanan** adalah berdasarkan presentasi dan fungsi sebagai Makanan seperti yang tersenarai di LAMPIRAN A.

Produk-produk dalam kategori makanan adalah dibawah pengawalan **Bahagian Keselamatan Dan Kualiti Makanan (BKMM), KKM.**

- 3.3 Kategori produk **Ubat** dengan presentasi dan fungsi sebagai ubat dimana:
 - Kandungan bahan aktif tanpa bahan makanan
 - Diformulasi dalam bentuk dos farmaseutikal (contoh: kapsul, tablet, serbuk, cecair, softgel, sublingual)
 - Mempunyai tuntutan kesihatan/ perubatan

Produk-produk dalam kategori **Ubat** adalah dibawah pengawalan **Pihak Berkuasa Kawalan Dadah (PBKD), KKM.**

- 3.4 Kriteria penentuan untuk produk **FDI** sebagai produk **Ubat** adalah berdasarkan:
 - i. kandungan bahan dengan tuntutan kesihatan/ perubatan produk.
 - ii. kandungan bahan yang tersenarai di dalam *Negative List For Food* (seperti LAMPIRAN B) dengan/ tanpa tuntutan kesihatan/ perubatan produk.

Sila rujuk Carta Pengelasan Produk FDI (seperti LAMPIRAN C)

4. Berikutan dengan keputusan ini, maka:

- 4.1 Bagi produk Suplemen Kesihatan dan Tradisional yang tidak lagi dikategorikan sebagai produk Ubat,
 - i. Permohonan Pendaftaran Produk Baru (yang sedang dalam proses penilaian):
 - Pemohon diminta untuk menarik balik permohonan pendaftaran produk.
 - ii. Produk telah berdaftar:
 - Pendaftaran produk akan dibiarkan sehingga tamat tempoh pendaftaran atau pemohon boleh menarik balik pendaftaran produk berkenaan.
- 4.2 Surat Pekeliling berikut akan terbatal dengan penguatkuasaan pekeliling ini:-
 - i. Pekeliling Pengelasan Produk Madu Campuran Herba (Bil (1)dlm.BPFK/PPP/01/03 Jld.1 bertarikh 15 September 2010)
 - ii. Pendaftaran Produk Yang Berbentuk Pati (*Essence*) [Contoh : Pati Ayam/ Pati Ikan/ Pati *Ostrich*/ Pati Itik] (Bil (01) dlm BPFK/PPP/01/03 bertarikh 18 April 2008)

5. Sukacita diingatkan agar semua syarikat yang mengilang, mengimport atau memasarkan produk-produk berkaitan untuk memberi perhatian dan mematuhi keperluan undang-undang yang terlibat mengikut kategori produk-produk seperti yang ditetapkan.

6. Pekeliling ini berkuatkuasa pada tarikh keputusan Mesyuarat Jawatankuasa FDI Bil 2/2014 mulai **9 JULAI 2014**.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,



TAN ANN LING

Pengarah
Biro Pengawasan Farmaseutikal Kebangsaan
Kementerian Kesihatan Malaysia

- s.k 1) Pengarah Kanan Perkhidmatan Farmasi
Bahagian Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
- 2) Pengarah Kanan
Bahagian Keselamatan dan Kualiti Makanan
Kementerian Kesihatan Malaysia
- 3) Pengarah
Bahagian Perkhidmatan Farmasi (Kuatkuasa)
Kementerian Kesihatan Malaysia

PRODUK MAKANAN

1. Produk berasas makanan dengan/ tanpa campuran bahan aktif (contoh: herba, vitamin, mineral):
 - i. Produk minuman segera campuran gula dan krimer
Contoh: kopi, coklat, susu soya
 - ii. Produk pati haiwan/ essence (cecair)
Contoh: pati ikan haruan, pati ayam, pati *ostrich*, pati itik
 - iii. Produk minuman (*beverages*) tanpa perlu bancuh untuk diminum terus/ *ready to drink* tanpa dos pengambilan.
Contoh: minuman dalam tin/kotak
 - iv. Produk kordial untuk dibancuh dengan nisbah pencairan yang disyorkan.
Contoh: pati jus kurma, pati jus anggur
 - v. Produk cuka (cecair)
Contoh: cuka epal, cuka kurma
 - vi. Produk madu (cecair)
2. Produk minuman tenaga (*energy drink*), produk minuman isotonik (*isotonic drink*), produk makanan untuk sukan (*sports nutrition*) dan produk makanan bertujuan khas (*Special Purpose Food*).
3. Produk dalam bentuk konvensional makanan
Contoh: Biskut, kek, produk coklat, gula-gula, *gummies*, *mee*
4. Produk untuk kegunaan masakan dan sediaan masakan
Contoh: Minyak (zaitun/ kelapa/ bunga matahari), serbuk kunyit
5. Produk herba, rempah ratus dalam bentuk mentah (*crude*)

Agensi yang mengawal:

Bahagian Keselamatan dan Kualiti Makanan
Kementerian Kesihatan Malaysia
Aras 4, Menara Prisma,
No. 26, Jalan Persiaran Perdana,
Presint 3, 62675 Putrajaya

(<http://www.fsq.moh.gov.my>)

LAMPIRAN B

NEGATIVE LIST FOR FOOD

- *Gamat*
- *Gypsum Fibrosum*
- *Red Yeast Rice*
- *Natto extract*
- *Placenta*
- *Pearl*
- *Bile (Hempedu)*
- *Glucosamine*
- *Hyaluronic acid*
- *Glutathione*
- *Gamma-amino Butyric Acid (GABA)*
- *Resveratrol*
- *Actaea racemosa (Fresh or dried rhizomes and roots or their extract)*
- *Artemisia Spp. (all species) (Leaf)*
- *Azadirachta indica (Seed)*
- *Brucea javanica, Brucea amarissima (Dried fruits & Seed)*
- *Bufo gargarizans Cantor, Bufo melanostictus Schneider, Bufo vulgaris Lour (Venom, Dried secretion, whole body)*
- *Chelidonium majus (Dried, whole or cut aerial parts)*
- *Conium maculatum (Whole Plant)*
- *Coptis chinensis, Coptis teeta (Rhizome)*
- *Croton tiglium L (Fruit seeds and oil)*
- *Datura spp. (all species) (Leaf, seed, Dried and leaf flowering or fruiting parts with branches)*
- *Digitalis spp.(all species) (Leaf)*
- *Dryobalanops lanceolata Burck*
- *Fritillaria spp.*
- *Gelsemium semperi virens*
- *Hypericum perforatum*
- *Mahonia aquifolium, Mahonia repens, Mahonia nervosa*
- *Melanorrhoea usitata Wall.*
- *Mucuna pruriens*
- *Mylabris phalerata, Mylabris cichorii*
- *Nerium indicum*
- *Nerium oleander*
- *Phellodendron amurense, Phellodendron chinense*
- *Plumbago indica*
- *Plumbago zeylanica*
- *Psilocybe cubensis*
- *Sanguinaria canadensis*
- *Scilla sinensis*
- *Sophora tomentosa*
- *Spigelia marilandica*
- *Strophanthus spp.(all species)*
- *Symphytum peregrinum*
- *Strychnos ignatii,*
- *Strychnos lucida,*
- *Strychnos roberans*

Notes:

1. This list :
 - is a compilation by the food-drug interphase (fdi) committee.
 - is comprehensive and non-exhaustive.
 - shall/ can be amended 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, which include but not limited to the following:
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 - c) Dangerous Drugs Act 1952;
 - d) Poisons Act 1952;
 - e) Medicines (Advertisement & Sale) Act 1956;
 - f) Patents Act 1983;
 - g) Wildlife Conservation Act 2010 (Laws of Malaysia Act 716); and
 - h) International Trade in Endangered Species Act 2008 (Act 686).
 - i) Food Act 1983 (Act 281) & Regulations
2. The written laws shall take precedence over this guidance document in any event of discrepancy.

CLASSIFICATION APPLICATION

- * *Application form for FDI product classification is available at www.bpfk.gov.my → Industry → Application Form → BPFK 300*
- * *Complete application form can be submitted either through:*
 - Email: classification@bpfk.gov.my or
 - Fax : 03 - 7958 1312 or
 - Mail : Centre for Product Registration, National Pharmaceutical Control Bureau, Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.
- * *Any enquiries & correspondence, please email to classification@bpfk.gov.my*

CLASSIFICATION APPLICATION



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National Pharmaceutical Control Bureau
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National Pharmaceutical Control Bureau Ministry of Health Malaysia
Biro Pengawalan Farmaseutikal Kebangsaan, Kementerian Kesihatan Malaysia

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- Inspection
- Licensing
- New Products/Indication
- Laboratory & Quality Control
- Application Forms
- Clinical Trial

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General Information

Drug Registration Guidance Document (DRGD)

The DRGD is the reference for both pharmaceutical and human use and traditional products.

[more...](#)

Registration and Notification

- QUEST system
- Medicinal Products
- Cosmetics
- Veterinary
- Template/Guide for

- General Information
- Drug Registration Guidance Document (DRGD)
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- Good Laboratory Practice (GLP) Compliance Monitoring Programme

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- Licensing
- New Products/Indication
- Laboratory & Quality Control
- Application Forms**
- Clinical Trial
- Good Laboratory Practice (GLP) Compliance Monitoring Programme

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Application Forms

Search Term:

General Forms:

No	Document Name	Type	Size
1.	BPFK 420.1 Borang Permohonan Pendaftaran Semula Produk Quest 3		0.10 MB
2.	BPFK-505 Set Up for Biological Based Product Manufacturing Facility Letter of Intent	dotx	0.06 MB
3.	BPFK 416.4: APPLICATION FOR VARIATION OF REGISTERED TRADITIONAL AND HEALTH SUPPLEMENT PRODUCTS		0.04 MB
4.	BPFK 415.3: Change In Manufacturing Site		0.03 MB
5.	BPFK 436.3: Permohonan Tambahan Indikasi Untuk Keluaran-Keluaran Berdaftar/Modified Nov 2013		0.02 MB
6.	BPFK 416.3: Minor Variation Notification Form for Pharmaceutical Products		0.03 MB
7.	BPFK 416.3: Minor Variation Notification Form for Pharmaceutical Products		0.02 MB
8.	BPFK 300 : Borang Pengkelasan Produk 2013		0.28 MB
9.	BPFK 300 : Borang Pengkelasan Produk 2013		0.06 MB
10.	BPFK 438.1 (T) : Permohonan Bagi Produk Tradisional Untuk Tujuan Eksport Sahaja (FEO)		0.07 MB

Summary

* Food products are not categorized as FDI products

A. Food based products:

- I. Instant drink products containing sugar and creamer
- II. Meat essence products (liquid)
- III. Ready to drink products (beverages) without dosing instruction in cheered pack/ canned / packet drinks.
- IV. Cordial products with recommended dilution ratio
- V. Vinegar products (liquid)
- VI. Honey products (liquid).

B. Energy/Isotonic drink, Sports Nutrition and Food for Special Purpose

C. Conventional Food Forms

D. Products used for cooking and food preparations

E. Herbs and spices in crude form

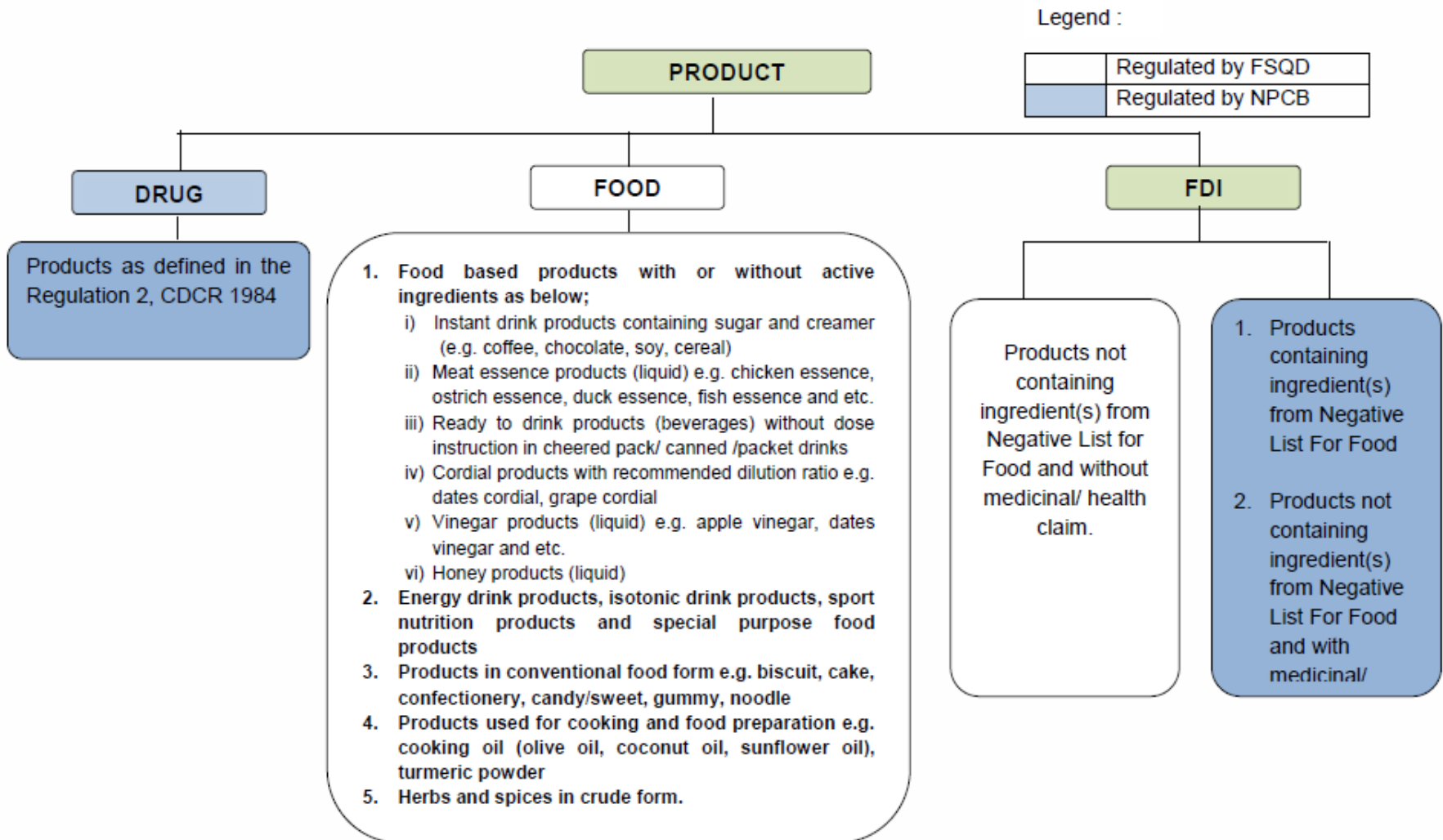
Summary

- * Classification for FDI products are based on criteria,
 - Negative List for food
 - Medicinal/ health claim

Summary Table of FDI Classification

DRUG	NON-DRUG
Contain active ingredient and with medicinal/health claim	Not containing Active ingredient from Negative List For Food and NO medicinal/ health claim
Contain Active ingredient listed in Negative List for Food with medicinal/ health claim	
Contain Active ingredient listed in Negative List for Food without medicinal/ health claim	
Formulated in pharmaceutical dosage form (eg. tablet, capsule, liquid,softgel, sublingual, etc)	
When there is greater uncertainty regarding the safety of an FDI product, such shall be regulated by NPCB. This is to enable closer monitoring of such products, so as to safeguard the interest of the consumer.	

CLASSIFICATION FLOW CHART



Thank you

