

New Regulations about Food Supplements & Herbal Products

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New Regulations about Food Supplements & Herbal Products

History (1)

Decree # 11710 issued 22 January 1998

- Subject: Regulate import of Natural Medicinal Products and Food Supplements.
- Formation of specialized committee to:
 - Set requirements for licensing these products
 - Classification criteria based on Upper Safe Levels.
 - Review applications and give recommendations.
 - Issue Licences
- Two main interruptions:
 - Temporary suspension Jan. 2000 - Nov. 2001
 - Early 2009 till March 2011.

New Regulations about Food Supplements & Herbal Products



History (2)

Many Decisions and Memos were issued and later cancelled:

- Decision # 844/1 dated 1 Sept. 2010 (Shipment in Refrigerated containers)
- Decision # 272/1 dated 14 Mar. 2011 (Committee and its duties)
- Decision# 940/1 dated 29 Sept. 2011 (General)
- Decision# 1897/2 dated 8 Oct. 2012 (Committee meetings – Website)
- Memo# 66 dated 28 Jun. 2013 (Re Decision # 940/1 – Sticker & Inspection)
- Memo# 3 dated 29 Jan. 2014 (Related to Decision # 940/1 - Sticker)
- Decision# 1378/1 dated 15 Jul. 2015 (Files for locally manufactured products)

New Regulations about Food Supplements & Herbal Products



Comparison with Pharmaceuticals

- Simplified Registration/Licencing file.
- Prices not fixed by MOH
- Sale outlets not restricted to pharmacies except when Committee requests that.
- Advertisement in public media could be permitted but ONLY after obtaining a special approval from MOH.

New Regulations about Food Supplements & Herbal Products



Applicable Regulations (1)

Law # 530 issued 21 July 2003

Article 4:

- Decree to set standards for classification and to differentiate Pharmaceutical Products from Natural Medicinal Products & Food Supplements.
- Decisions for registering & importing these products separate from the decisions for registering & importing Pharmaceutical Products.

New Regulations about Food Supplements & Herbal Products



Applicable Regulations (2)

Law # 90 issued 6 March 2010

- Amend Article 37 of the Law of Practice of Pharmacy # 367.
- Clarifies the scope of the products involved.
- Forbids Advertisement and Commercial Promotion for products with therapeutic effect.

New Regulations about Food Supplements & Herbal Products



Applicable Regulations (3)

Decree # 5518 dated 14 Dec. 2010

- Replaces Decree # 11710 of 1998.
- New Committee Structure.
- Addresses all the gaps and latest developments
- Categorize the products
- Covers Import, Manufacturing, Packaging and Packing.
- Forbids advertisement in all Public Media unless permission is obtained from MOH.

New Regulations about Food Supplements & Herbal Products



Applicable Regulations (4)

Decision # 2011/1 dated 24 Oct. 2017

- Subject: Food Supplements and Natural Products with Medicinal Benefits.
- Categories:
 - Diet Products
 - Vitamins & Minerals
 - Concentrated Foods
 - Sports Nutrition
 - Uppers other than Pharmaceuticals
 - Energy Drinks
 - Natural Plants & Herbs with medicinal benefits
 - Other Food Supplements like Probiotics, Omega 3, Co Q10, DHA ... etc.
 - Hormones from plant sources like Melatonin, DHEA ... etc.

New Regulations about Food Supplements & Herbal Products



Applicable Regulations (4) cont'd

- Requirements for licensing.
- Committee meetings.
- Flexibility for size or flavor variations.
- Use of most strict Upper Safe Level for Vitamins & Minerals
- Shipment in Refrigerated containers : 1 June till 30 Sept. (B/L date)
- Page on MOH Website.
- Sticker «هذا المستحضر هو متمم غذائي وليس دواء»
- Mentions GSDF – Draft issued by MOH.
- Forbids Energy Drinks that contain Alcohol.
- Inspection & Control at the request of MOH Health Engineering Dept. مصلحة الهندسة الصحية
 - At Warehouses and in Market by the Health Inspectors. المراقبين الصحيين
 - In Pharmacies & Pharmaceutical Plants by the Pharmacy Inspection Department. التفتيش الصيدلي

New Regulations about Food Supplements & Herbal Products

Sticker developed by Syndicate

hi health
insight 2018

