



Pre-importing License for Special Food Guideline

Public Health Directorate

Nutrition Section

November 2022

Pre-importing License for Special Food Guideline

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Introduction

The Nutrition Section in the Ministry of Health in the Kingdom of Bahrain frequently works on developing their procedures to make it efficient for agents and business holders to submit requests for licensing and importing special food in the kingdom of Bahrain.

This Guideline documents are meant to provide assistance to industries and professionals on how to comply with governing statutes and regulations. The purpose of this guideline is to provide clear instruction on the Nutrition Section- Public Health directorate procedures for licensing and update of Special Food.

Guideline Scope

This guideline is made for special food product which are defined as food or food ingredients that claim to give physiological benefits that gives a higher beneficial value in promoting health and protects or lowers chances from diseases. Special food comes in different forms.

Special Food Types

Special food	Definitions
1) Foods for infants and young children (0-36 months)	Breast milk substitute and complementary foods for infant and for young children (0-36 months).
2) Foods for use in weight control diets	Special food for weight loss, weight gain and products for diabetes.
3) Sport supplements	Special food for improving athletic performance and build muscle.
4) Energy drinks	Energy drinks promoted as raising the level of mental and physical activity. Contained a high percentage of caffeine, sugar or artificial sweeteners is a basic basics component and it contains additional ingredients that give stimulating properties such as taurine, guarana, ginseng, and glucuronolactone.
5) Vitamins and mineral supplements	Special food containing one or more vitamins or minerals.
6) Carbohydrates, protein, and fats supplements	Special food that contain fatty acids, amino acids, or carbohydrates.
7) Foods with health or nutritional claims	Special food that provides physiological benefits beyond basic nutritional functions.
8) Others	Other supplements for nutritional and health purposes.

Producers on Submitting for Pre-importing License Decision

First: Before submission

Applicants should fill out a special food checklist (appendix1) and prepare all documents listed below because they are mandatory requirements **without them product study and decision procedures cannot be completed:**

Mandatory Requirements
• Copy of commercial registration certificate.
• Copy of certificate to practice commercial activities under health surveillances import, export in sale of functional healthy food.
• Copy of the agent (applicant) identity (CPR).
• Two copies of colored clear Mocks-ups of outer label (artwork), inner label and packaged leaflet (with company signature and stamp).
• Labelling and adjoining explanatory statements shall be in Arabic and, where another language is used, it shall be alongside the Arabic. All the information provided in another language shall be identical with those written in Arabic.
• Products under NHRA classification: Official and valid Health product classification letter (signed and stamped) issued from national health regulatory authority (NHRA).
• Free sale certificate: with marketing date must be legalized or declaration from issuing authority and by the embassy of the Kingdom of Bahrain in the country of origin or embassy of any Arab country.
• Lab analysis for product composition content (with exact composition per serving, source and function of each ingredient) from accredited lab. (Good laboratory practice could be required) Lab file must be provided from the company not external.
• Valid legalized good manufacturing practice certificate/ manufacturing license of the manufacture from country of origin.
• Sample of the product should submitted if required.
• Any other required documents.

Documents requirements If available
• A previously issued certificate for the same product from nutrition section.
• Copy of licensed certificate issued by one of the GCC countries.

Second: Validation & submission

- ↓ The Pre-importing license application should be submitted through the customs single window for trade (OFOQ Bahrain).
- ↓ Determining the right HS-code of the product (that are related to nutrition section (appendix2)). HS-code it is a number that includes names of Goods, their description and distinction, and the categories of customs duties to which they are subject. It is used to classify goods and determine their customs tariffs. For more information, visit the website of the Customs Affairs in the Kingdom of Bahrain
- ↓ The attachments of all the mandatory requirements mentioned in the first point must be entered through the customs single window for trade (OFOQ Bahrain).
- ↓ The nutrition section will review the application along with all required documents. Any missing mandatory documents will result in rejection of the application.

Third: Assessment and Queries

- ↓ Product is assessed in accordance with Nutrition Section-public health standard operating procedures, accredited references and legislations.
- ↓ During the period of studying the product, if any queries are raised, a request for further information will be emailed to the applicant. The applicant will have a time limit of thirty days unless if the agent requests an extension through the email. The absence of any response will result in rejection of the application and will require resubmission.

Fourth: Licensing certificate

- ↓ Special food license decision will take a maximum of thirty working days to be proceeded, however in some cases the time limit may differ due to some products that may require further evaluation.
- ↓ Special Food pre-importing license is made by one of the following decisions::
 - 1) Approve: with the validity of five years
 - 2) Disapprove: Applicant will have a maximum of thirty days to send an official letter to the Nutrition section in public health to re-consider the decision of the products with the reason.

- ↓ Any changes accrued in the product composition/quantity or changes in the label, pack size or any other changes will require the agent to re-submit for a new registration application.
- ↓ The Safety, import and clearance of the product falls under food control department.

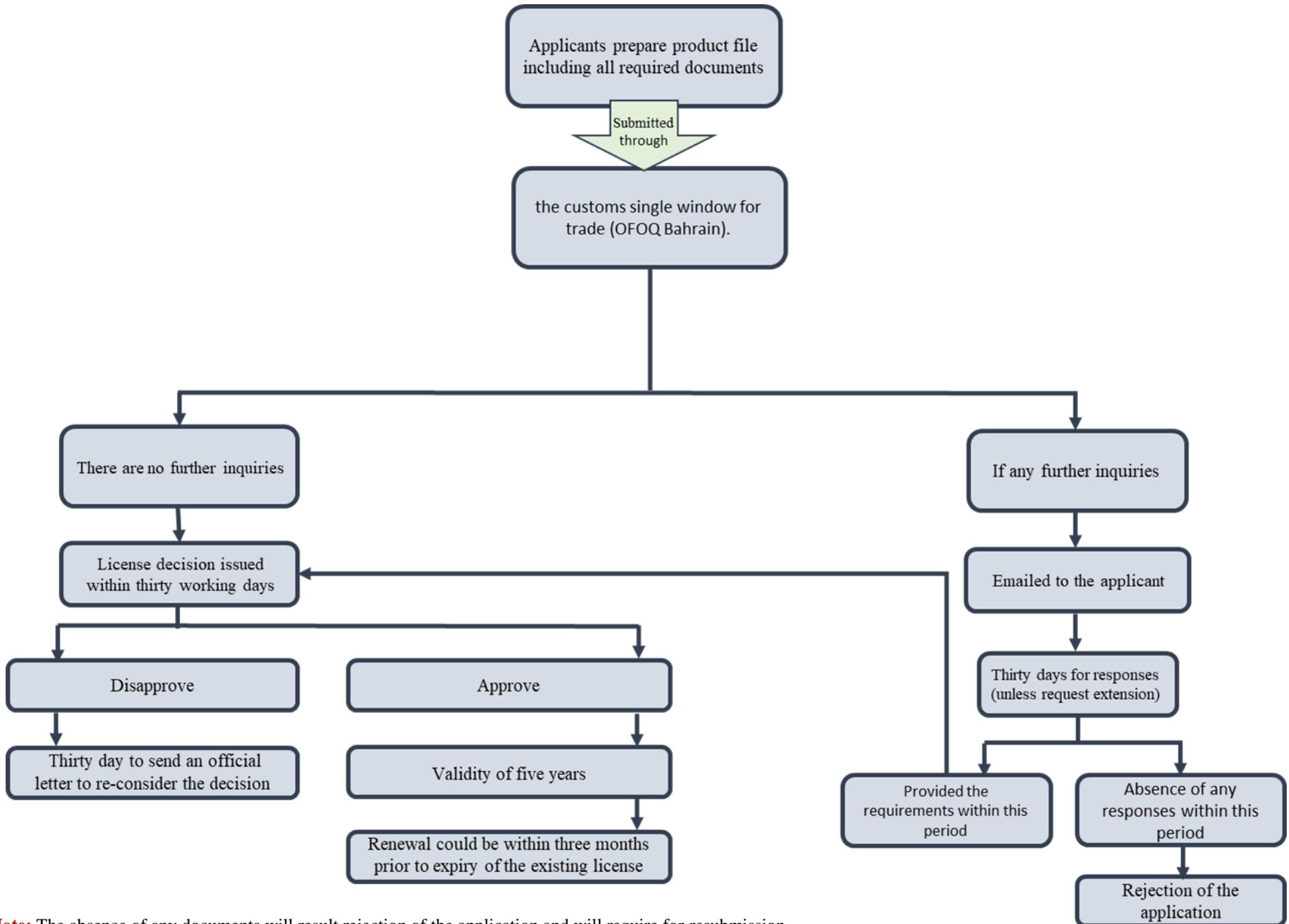
Five: Import and clearance

Food control section are responsible authority for the procedures and policy regarding the food safety, importation and clearance regulations.

Six: Renewal of special food licenses

Applicants are required to renew Special Food license every five years of its issuance. Nutrition Section-Public Health encourages the applicant to submit the renewal application within three months prior to expiry of the existing license. It is the responsibility of the applicant to adhere to these timelines.

Producers on Submitting for Pre-importing License Decision Diagram



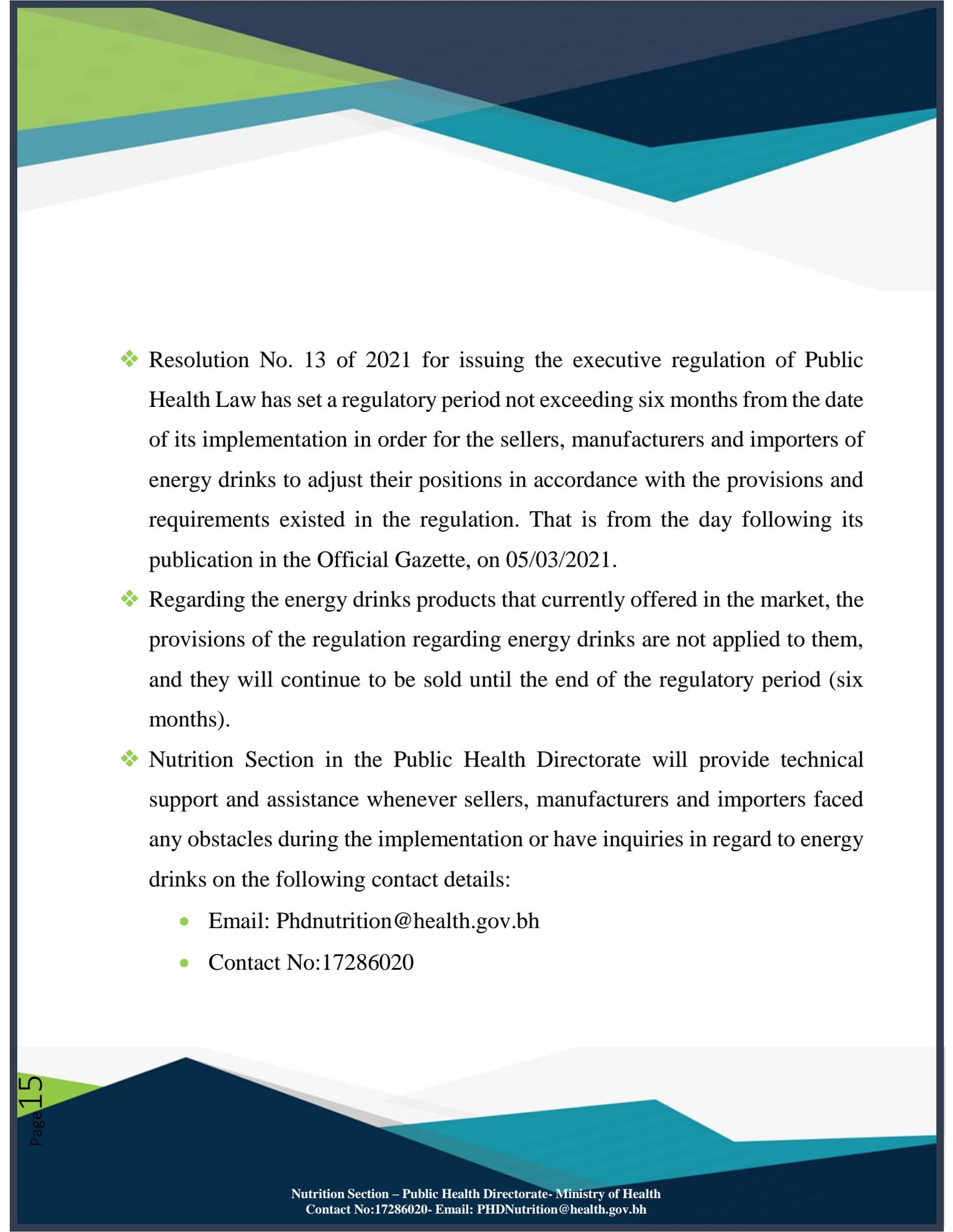
Note: The absence of any documents will result rejection of the application and will require for resubmission.

General Restriction

- ❖ All products will be assessed by scientific guidelines by the nutrition section in the Ministry of Health. According to local regulations and laws, GCC standards, as well as national regulations and accreted references.
- ❖ All required documents must be legalized or have a declaration from issuing authority when submitting documents through the customs single window for trade (OFOQ Bahrain). Failure to provide the necessary materials/information will result in delay or cancellation of the application.
- ❖ When submitting a license application through the customs single window for trade (OFOQ Bahrain), consideration must be given to choosing the (multiple license type) in order to be able to enter the shipments of the approved product over a period of five years.
- ❖ It is mandatory to provide accredited lab (Appendix (3)) analysis certificate for the product. Laboratory analysis dossier (lab documents) which should be issued by the manufacture company and not the importer.

- ❖ The product label must include the following:
 - The name of the product.
 - List of active and inactive ingredients
 - Nutritional data
 - Net contents
 - The name and the address of the manufacturer or the packing factory
 - Country of origin
 - Date marking and instructions for storage and use
 - Special food label must be subject to the GCC Standards /Technical regulations and equivalents.
- ❖ It is forbidden to market or claim that the product is licensed by the ministry of health or use the logo of the ministry of health on the package of the product.
- ❖ Any changes accrued in the product composition/quantity or changes in the label, pack size or any other changes will require the agent to re-submit for a new registration application.
- ❖ Marketing Special Food is not allowed unless approval is given from the Nutrition section –Public health directorate (appendix 4).
- ❖ The Safety, import and clearance of the product falls under food control section.

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- ❖ In regards to energy drinks, it is prohibited to do any of the following actions:
 - It is prohibited to sell it to persons under 18 years, all retail shops that sell energy drinks directly to consumers, should put in a prominent place a clear, legible statement in both Arabic and English language that it is not allowed to sell for persons under 18 years based on their regulations.
 - It is prohibited to sell it in restaurants and canteens at health and educational institutions.
 - ❖ Manufacturers and importers of energy drinks should add the following cautionary statement on the label of Energy Drinks in a prominent way in both Arabic and English language: “not suitable for pregnant or lactating women, persons under 18, years persons with sensitivity to caffeine or any other product components, or those who suffer from diseases that may affect their health especially Cardiovascular Disease patients, diabetics, and athletes during exercise”

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- ❖ Resolution No. 13 of 2021 for issuing the executive regulation of Public Health Law has set a regulatory period not exceeding six months from the date of its implementation in order for the sellers, manufacturers and importers of energy drinks to adjust their positions in accordance with the provisions and requirements existed in the regulation. That is from the day following its publication in the Official Gazette, on 05/03/2021.
 - ❖ Regarding the energy drinks products that currently offered in the market, the provisions of the regulation regarding energy drinks are not applied to them, and they will continue to be sold until the end of the regulatory period (six months).
 - ❖ Nutrition Section in the Public Health Directorate will provide technical support and assistance whenever sellers, manufacturers and importers faced any obstacles during the implementation or have inquiries in regard to energy drinks on the following contact details:
 - Email: Phdnutrition@health.gov.bh
 - Contact No:17286020

Special Food Advertising Restriction

Marketing Special Food in any way of advertising whether it is (audible, visual, readable) is not allowed unless approval is given from the nutrition section according to the following:

- ❖ The content of the advertisement must be consistent with the products uses and the scientific evidence of its effectiveness.
- ❖ The advertisement should not include any exaggeration, deceptive, misleading messages.
- ❖ The advertisement should not encourage any unhealthy diet and lifestyle behaviors.
- ❖ The advertisement cannot be marketed directly or indirectly in a way that can cause harm to another product.
- ❖ The advertisement should not conflict with any cultural believes and behavior.
- ❖ After assuring that the marketing request compliant with the requirements of marketing Special foods. The period, layout and information in the advertisement must be mentioned in the license (appendix 4).
- ❖ In case the advertisement violated the given license, the nutrition section will take an action against the violated company.



Date:

PH/FC/ / NU - /2022

Special Food Application and checklist
استمارة تقديم طلب ترخيص الأغذية الخاصة ومافي حكمها وقائمة المتطلبات

embassy of the Kingdom of Bahrain in the country of origin or embassy of any Arab country.	
• Lab analysis for product composition content (with exact composition per serving, source and function of each ingredient) from accredited lab. (Good laboratory practice could be required) Lab file must be provided from the company not external.	• ملف التحليل المخبري للمنتج لمحتوى تكوين المنتج (مع التركيب الدقيق لكل عنصر، ومصدر ووظيفة كل مكون) من المختبر المعتمد. (قد يتم طلب شهادة ممارسة مخبرية جيدة). ملف التحليل يتم توفيرها من قبل الشركة المنتجة فقط.
• Valid legalized good manufacturing practice certificate/ manufacturing license of the manufacture from country of origin.	• شهادة ممارسة التصنيع الجيد غير منتهية الصلاحية موقعة ومختومة من جهة معتمدة ومرخصة في بلد المنشأ ، تثبت ترخيص التصنيع للمصنع.
• Sample of the product should submitted if required.	• إرفاق عينة من المنتج في حال طلب الإدارة المختصة.
• Any other required documents.	• أية مستندات أو بيانات أو معلومات أخرى تطلبها الإدارة المختصة.

Documents requirements If available (إن وجدت) المستندات التي يجب توفرها

• A previously issued certificate for the same product from nutrition section.	• نسخة من شهادة ترخيص سابقة صادرة للمنتج من قبل قسم التغذية.
• Copy of licensed certificate issued by one of the GCC countries.	• نسخة من شهادة ترخيص سابقة صادرة للمنتج من إحدى دول الخليج العربي

إقرار Declaration

- I declare that all the information supplied on the form and the documents attached are correct and I, under this declaration, grant the ministry of health (MOH) the right to verify the information included in my portfolio.
أقر بأن جميع المعلومات المقدمة والمستندات المرفقة صحيحة و بموجب هذا الإقرار بحق لوزاره الصحة التحقق من صحتها إن لزم.
- I declare that the product is free of any banned hazardous substances that harm consumer health.
أقر بأن المنتج خال من أي مواد ممنوعة ومحظورة تضر بصحة المستهلك.
- Products that are under NHRA calcification: I declare that I attached all the documents that I have submit to NHRH, attached artwork approved by NHRA.
للمنتجات الخاصة بتصنيف نهرا: أقر بأنني أرفقت جميع المستندات التي تم تقديمها للهيئة الوطنية لتنظيم المهن والخدمات الصحية (NHRA) وبأن غلاف المنتج مرخص من قبل الهيئة.
- All mentioned documents above will not be returned back to the agent once it have been submitted.
جميع المستندات المذكورة أعلاه لن يتم إعادتها لمقدم الطلب.
- The nutrition section is entitled to request any other document depending on the nature of the product.
يحق للقسم المعني بطلب أي مستند آخر وذلك بحسب طبيعة المنتج.

Importer name & signature:
تم المورد وتوقيع

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قسم التغذية - إدارة الصحة العامة - وزارة الصحة Nutrition Section - Public Health Directorate- Ministry of Health
الهاتف no Contact: 17282218 - البريد الإلكتروني Email: PHDNutrition@health.gov.bh

Appendix (2): HS-code of the product that are related to nutrition section

NO.	Special Food	HS-code
1	• Breast milk substitute	- 19011010
		- 19011090
		- 19011020
2	• Snacks for children	- 21069099
		- 20051010
		- 20071010
3	• Protein powder	- 21061000
4	• Energy drinks	- 22021024
5	• Food supplements	- 21069093
6	• Supplements that contain more than one vitamin	- 21069093
7	• Other food supplements for nutritional enhancement purposes	- 21069093
8	• Muscle growth supplement	- 21069096
9	• Protein hydrolyzed mainly from a mixture of amino acids and sodium chloride, and used in food preparations.	- 21069095
10	• Mineral water for athletes with added sugar or other sweeteners	- 22021013
11	• Vitamins (A) and their derivatives	- 29362100
12	• Vitamin (B1) and its derivatives	- 29362200
13	• Vitamin (B2) and its derivatives	- 29362300
14	• D - or DL - pantothenic acid (vitamin B5) and its derivatives	- 29362400
15	• Vitamin (B6) and its derivatives	- 29362500
16	• Vitamin (B12) and its derivatives	- 29362600
17	• Vitamin (C) and its derivatives	- 29362700
18	• Vitamin (E) and its derivatives	- 29362800
19	• Other vitamins and their derivatives	- 29362900
20	• Other, including natural concentrates	- 29369000

Appendix (3): Examples of laboratories accredited by the Saudi Food and Drug Authority (SFDA)

- ❖ Saudi Ajal Labs
- ❖ Element Materials Technology Saudi Labs
- ❖ The Stability Laboratory
- ❖ Saudi specialized laboratories Co.
- ❖ King Abdullah International Medical Research Center
- ❖ Bureau Veritas Company.
- ❖ Hasanah Specialized Labs Company
- ❖ Gulf Star laboratory
- ❖ Jubail International Laboratorys
- ❖ tcr Arabia Laboratory
- ❖ ALS Arabia laboratory
- ❖ Asure quality laboratory
- ❖ Al Ahly food industries
- ❖ Honey Quality Laboratory
- ❖ IDAC Merieux NutriSciences

Note: Laboratories must be accredited by a regional or global body or certified by the designated entities.

Appendix (4): Special food advertisement application template

إستمارة ترخيص دعابة و إعلان الأذنية الخاصة ومافى حكمها

Special food Advertisement License Form

وفقا للأذنة التذنية لقانون الصحة العامة الصادرة بالقانون رقم (34) لسنة 2018 الفصل السادس (الأذنية الخاصة ومافى حكمها المادة (16) و (17) فإذنة لا يجوز الإعلان عن الأذنية الخاصة و مافى حكمها بأية طريقة من طرق الإعلان - سواء كانت مسمومة أو مرئية أو مقروءة إلا بعد الحصول على ترخيص بذلك من الإدارة المختصة وفقا لشروط وإجراءات تم ذكرها فى المادة (16) من القانون.

According to the Public Health regulations which implementing in 2018 Law No. (34)Chapter Six (Special Foods and their equivalent Article (16) and (17), it is prohibited to advertise special foods or their equivalent in any way of advertising - whether audible or visual or readable except after obtaining a license from the responsible legalized authority under the conditions and procedures mentioned in Article (16) of the Law.

Application submission date:		تاريخ تقديم الطلب:
IMPORTANT: Failure to submit the necessary items/ information will delay the processing of your application. You must complete and submit all the requested information.		
هام : عدم تقديم المواد / المعلومات الضرورية سوف يؤدي إلى تأخير أو إلغاء طلبك. يجب عليك إكمال وتقديم جميع المعلومات المطلوبة .		
بيانات الإدارية Administrative data		
Applicant name (company name and address):		مقدم الطلب (اسم الشركة و عنوانها):
Applicant contact number and email :		رقم التواصل و البريد الإلكتروني لمقدم الطلب:
بيانات المنتج/المنتجات المراد الإعلان عنها Information about the product/(s) to be advertised		
Product name :		اسم المنتج :
Form :	<input type="checkbox"/> Solid صلب <input type="checkbox"/> سائل liquid <input type="checkbox"/> مسحوق Powder <input type="checkbox"/> الواج Bar <input type="checkbox"/> أقراص Tablets <input type="checkbox"/> أخرى Others	شكل المنتج :
A copy of valid issued certificate from nutrition section for the same product.	Required attached (Copy of the license along with the approved product label) مرفق مطلوب (نسخة من الشهادة مع غلاف المنتج الممتد)	نسخة من شهادة الترخيس غير متتهيه الصلاحيه الصادرة للمنتج من قبل قسم التغذية.
بيانات الإعلان Advertisement details		
Advertising publishing channel:	<input type="checkbox"/> التلفاز TV <input type="checkbox"/> الانترنت (أذكر الموقع) Internet (provide link) <input type="checkbox"/> وسائل التواصل الإجتماعية (provide account names) Social media (أذكر أسم الحساب) <input type="checkbox"/> الجريدة News Paper <input type="checkbox"/> Brochures or posters (please provide details of where it will be located) مطبوعات و ملصقات (أذكر مكان عرضها) <input type="checkbox"/> أخرى (الرجاء تحديدها) Others (please specify)	وسيله نشر الإعلان

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قسم التغذية - إدارة الصحة العامة - وزارة الصحة Nutrition Section - Public Health Directorate- Ministry of Health
الهاتف : 17282218 - البريد الإلكتروني PHDNutrition@health.gov.bh : Email

Advertising or marketing material if any such as: brochures, posters, booklets...etc.	Required attached مرفق مطلوب	المواد المستخدمة في الإعلان أو التسويق إن وجد مثل : المطويات أو الملصقات أو كتيبات...إلخ
Advertisement period of time:	(من)From : _____ (إلى)to: _____	الفترة الزمنية لنشر الإعلان:
Please mention the target people for the advertisement:		الرجاء ذكر الفئة المستهدفة من الإعلان:
Please briefly describe the proposed advertisement		الرجاء وصف محتوى الإعلان المقترح بطريقة مختصر
إقرار		
<p>I declare that all the information supplied on the form and the documents attached are correct and I under this declaration, grant the ministry of health (MOH) the right to verify the information included in my portfolio. أقر بأن جميع المعلومات المقدمة والمستندات المرفقة صحيحة و بموجب هذا الإقرار بحق لوزاره الصحة التحقق من صحتها إن لزم.</p>		
For use by nutrition section only فقط قسم التغذية		
Date of issuing the decision:		تاريخ صدور القرار:
Request Status:	Approved موافق <input type="checkbox"/> Rejected مرفوض <input type="checkbox"/>	حاله الطلب:
Comments (if any) التعليقات (إن وجدت)		

توقيع الدكتور بهينه العجلان-رئيس قسم التغذية
DR. Buthaina Al-Ajlan - Chief of Nutrition Section sign

توقيع مقدم الطلب
Applicant sign

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قسم التغذية - إدارة الصحة العامة - وزارة الصحة Nutrition Section - Public Health Directorate- Ministry of Health
الهاتف Contact no : 17282218 - البريد الإلكتروني Email : PHDNutrition@health.gov.bh

Appendix (5): Reference competent authorities in some countries

No.	Country	Authority
1.	Italy	Ministero Della Salute DGISAN
2.	Spain	AECOSAN & FSC from one of the notified bodies in the approved list
3.	Germany	BVL-notification & FSC from one of the notified bodies in the approved list
4.	Canada	Health Canada
5.	USA	Food and drug administration
6.	New Zealand	MEDSAFE
7.	UK	RURAL PAYMENT AGENCY
8.	France	Synadiet
9.	Switzerland	Swiss export control- competent authority
10.	India	1. Food safety & standards act 2. Drug control dept
11.	Poland	Chief Sanitary Inspectorate of the state Sanitary Inspection
12.	Egypt	Ministry of health
13.	Turkey	Food Supplements- Republic of Turkey Ministry of Food, agriculture & Livestock
14.	Philippines	FDA of Philippines
15.	Korea	Ministry of food and drug safety
16.	Cyprus	Ministry of health
17.	Japan	ministry of health labour and welfare
18.	UAE	Registration certificate - Dubai municipality
19.	Romania	Ministry of agriculture for medicinal herbs
20.	Thailand	FDA of Thailand
21.	Portugal	directorate general for food & veterinary
22.	Slovenia	MOH of Slovenia
23.	Australia	Cosmetics- Victorian Chamber of commerce & industry Therapeutic Goods Administration (TGA)
24.	Jordan	Jordan food & drug administration
25.	Oman	Directorate General of Pharmaceutical Affairs and Drug Control (DGPA&DC) at the Ministry of Health (MOH)
26.	Saudi Arabia	Drug sector Saudi food & drug authority