

# 特殊營養食品查驗登記申請書

## APPLICATION FORM FOR REGISTRATION OF SPECIAL DIETARY FOODS

受文者：衛生福利部

Recipient: Ministry of Health and Welfare

主旨：本公司擬由「(原製造廠國別及名稱)」製造「(中文品名)」食品一種，申請審核認可為特殊營養食品。

Subject: Application for registration of (Product Name in Chinese) manufactured by (Country of origin and name of original manufacturer).

申請案類別（請擇一勾選）：Application classification (please choose one)

（一）嬰兒與較大嬰兒配方食品：Infant formula and Follow-up infant formula

☐嬰兒配方食品 Infant formula、☐較大嬰兒配方輔助食品 Follow-up infant formula、☐特殊醫療用途嬰兒配方食品 Infant formula for special medical purposes。

（二）特定疾病配方食品：Formula for certain disease

☐營養均衡完整配方食品 Nutritionally complete food with balanced formula、☐營養調整完整配方食品 Nutritionally complete food with customized formula、☐營養調整補充配方食品 Nutrition adjusted supplementary formula food、☐特殊單素配方食品 Special modular formula food。

說明：檢附之文件、資料及樣品如下(打☑記號者)：

Description: The attached documents and information include (ticked items)

- ☐（一）申請書表乙份。Application form, one copy.
- ☐（二）原料成分含量表正本乙份。Original copy of the ingredient list.
- ☐（三）產品規格表正本乙份。Original copy of the product specification.
- ☐（四）營養成分分析表正本乙份。Original copy of the nutrients analysis report.
- ☐（五）製程作業重點資料乙份。Manufacturing process summary, one copy.
- ☐（六）原製造廠為合法工廠之官方證明文件乙份。Original copy of the official certificate verifying the legitimacy of the original manufacturer.
- ☐（七）委託製造者，其委託證明文件正本。A contract manufacturer is required to provide the original copy of the manufacturing contract.
- ☐（八）產品中文標籤、外盒包裝及說明書各二份(每一規格、型態、材質均應檢附；說明書內容相同者，得檢送任一規格、型態、材質者之說明書)。If the product on the application will be available in different packaging specifications, forms and materials, the applicant is required to submit two copies of Chinese product label, box packaging, and user instructions for each specification, form and material. However, if the products in different specifications, forms and materials have identical user instructions, the applicant does not need to submit replicate copies.
- ☐（九）申請廠商公司登記或商業登記證明文件影本乙份。Photocopy of the applicant's company registration or business registration certificate.
- ☐（十）完整樣品：有不同包裝規格、型態或材質者，各別檢附之。Where the complete sample is available to the market in different packaging specifications, forms or materials, the applicant is required to submit one sample for each option.
- ☐（十一）申請產品於國內再分裝者，並檢附下列文件及樣品：Where the product will be re-packed in new containers for sale in Taiwan, the following documents and sample shall be additionally submitted：

- ☐1.輸入之產品，原製造廠出具分裝證明或同意文件正本乙份。The manufacturer's original copy of the repacking certificate or document of consent to product repacking for imported products.
- ☐2.國內分裝工廠之工廠登記證明文件影本，且該文件應登載有關食品分裝、加工或製造項目乙份。The domestic repacking facility's factory registration certificate in photocopy. Food repacking, processing or manufacturing shall be listed in the scope of business stated on the factory registration certificate.
- ☐3.中央主管機關認有必要者，由中央主管機關認可之檢驗機構最近一年內出具之分裝樣品營養成分分析表正本乙份。Where the competent central authority deems necessary, the applicant may be required to submit the original copy of the nutrients analysis report on the repackaged sample issued by an inspection body approved by the competent central authority within one year.
- ☐4.分裝產品中文標籤、外盒包裝及說明書等各二份(每一規格、型態、材質均應檢附；說明書內容相同者，得檢送任一規格、型態、材質者之說明書)。If the re-packed product on the application will be available in different packaging specifications, forms and materials, the applicant is required to submit two copies of Chinese product label, box packaging, and user instructions for each specification, form and material. However, if the products in different specifications, forms and materials have identical user instructions, the applicant does not need to submit replicate copies.
- ☐5.分裝後樣品：不同分裝規格、型態、材質者，各別檢附之。Where the repacked product sample is available in different packaging specifications, forms and materials, the applicant is required to submit one sample for each option.
- ☐ (十二)特殊營養食品查驗登記資料表乙份。List of registration information for special dietary foods, one copy.
  - ☐1.特殊營養食品仿單標籤粘貼表二份。Table for pasting of instruction manual and label for special dietary foods, two copies.
  - ☐2.切結書乙張。Affidavit, one copy.
- ☐ (十三)申請**嬰兒與較大嬰兒配方食品**者，應檢附於國外販售之證明文件及產品乙份，或有效樣本數二十人以上之試用報告乙份。For Infant formula and follow-up infant formula, the applicant is required to submit the original substantiating document verifying the product is for sale in a market outside the territory of Taiwan and a product sample, or a trial report of the product with a valid sample size of more than 20 subjects.
- ☐ (十四)申請**特定疾病配方食品，除營養均衡完整配方食品者外**，應另檢附：For Formula for certain disease, all applicants, except for nutritionally complete food with balanced formula, are required to submit the following：
  - ☐1.產品適用對象因疾病或醫療狀況導致特定營養素或成分需求之說明及佐證資料。Information on the specific nutritional requirement for intended product users that would otherwise not be met without the product due to illness or medical conditions, along with supporting documents.
  - ☐2.產品適用對象之特定營養素或成分需求難以日常飲食達成之說明及佐證資料。Information on why the intended users cannot otherwise meet the specific nutritional requirement described in the preceding subparagraph from the daily diet, along with supporting documents.
  - ☐3.產品設計原理。The mechanism behind the product design.
  - ☐4.產品使用方式及食用量可達成(十四)1.及 2.之說明及佐證資料。Information on how the intended use and quantity of intake of the product help the users to achieve the

objectives described in subparagraphs (1) and (2) of this paragraph, along with supporting documents.

☐5.臨床人體食用研究報告乙份。Clinical study report for the product under applicant, one copy.

☐ (十五) 申請**特定疾病用之高蛋白質食品**，應提供蛋白質效率 (Protein Efficiency Ratio, PER)、蛋白質經消化率修正的胺基酸評分值 (Protein Digestibility Corrected Amino Acid Score, PDCAAS) 或其他國際間認可之蛋白質測定方法。

For high-protein disease-specific formulas, the applicant is required to provide information on the protein efficiency ratio (PER), protein digestibility corrected amino acid score (PDCAAS) or other internationally-recognized protein determination indicators.

☐ (十六) 申請案電子檔案(光碟一式二份)。Electronic records of the application (Optical disk in duplicate)

☐ (十七) 其他必要之文件 Other essential documents ( )。

備 註 Remarks :

1. 詳細之申請手續，請依本部「**食品與相關產品查驗登記及許可文件管理辦法**」辦理。For detailed application procedures, please follow the MOHW's Regulations for 「REGULATIONS GOVERNING THE MANAGEMENT OF THE REVIEW, REGISTRATION AND ISSUANCE OF PERMIT DOCUMENTS FOR FOOD AND RELATED PRODUCTS」
2. 上述文件或資料，以非英文之外文記載者，應檢附立案翻譯社出具之中文或英文譯本。Documents and information mentioned above in languages other than English and Chinese shall be accompanied with English or Chinese translations provided by a registered translation agency.

申請商號	:	蓋章
Name of the Applicant	:	(Company Seal)
負責人	:	蓋章
Responsible Person	:	(Seal)
食品業者登錄字號	:	
Food Business Registration Number	:	
地址	:	
Address	:	
電話	:	
Telephone Number	:	
連絡人 姓名	:	
Contact Name	:	
Person 電話	:	
Telephone Number	:	
電子郵件	:	
E-mail	:	

中 華 民 國 年 月 日

Date ( yyyy / mm / dd )

# 切 結 書 AFFIDAVIT

茲於\_\_\_\_年\_\_\_\_月\_\_\_\_日向

貴部申請特殊營養食品查驗登記，

This affidavit is made to apply to the Ministry of Health and Welfare for registration of the following special dietary foods on \_\_\_\_\_ (Date):

中文品名 Food Name in Chinese : \_\_\_\_\_

英文品名 Food Name in English : \_\_\_\_\_

保證該產品所使用之名稱、商標、圖案、標籤、仿單、包裝、標示等，並無仿冒或影射他人已註冊之商標等情事，且所提供之文件資料亦均屬實，如有違法，除應自負法律上一切責任外，並同意貴部撤銷該品之查驗登記。 此 據

謹 呈

衛生福利部

The affiant herein states that the name, trademark, pattern, label, instruction manual, packing and marking of the above product do not imitate or infringe any trademarks registered by other parties, and that the documents and information provided by the affiant are true and authentic. The affiant is willing to assume full responsibilities for any violations and accept the decision of the Ministry of Health and Welfare to revoke the registration.

To: Ministry of Health and Welfare

具 切 結 商 號 Affiant :

蓋 章 (Company Seal)

負 責 人 Responsible Person :

蓋 章 (Seal)

營利事業統一編號 Unified Business Number :

地 址 Address :

電 話 Telephone Number : ( )

聯 絡 人 姓 名 Contact Person :

電 話 Telephone Number : ( )

中 華 民 國 年 月 日

Date ( yyyy / mm / dd )

## LIST OF REGISTRATION INFORMATION FOR SPECIAL DIETARY FOODS

[illegible]

營利事業統一編號 Unified Business Number																					
商 號 名 稱 Name												負 責 人 Responsible Person			電 話 號 碼 Telephone Number						
地 址 Address		<input type="text"/>																			

[illegible]

Fill out the "Unit" column with Arabic number: ①%, ②kg, ③gm, ④mg, ⑤mcg, ⑥Other \_\_\_\_\_

[illegible]



## 填 表 說 明 Note

本表為配合本部特殊營養食品電腦作業而設。申請商申請時應就「套藍」部份，一格一字詳實填寫茲說明如下：

The table is produced in line with the special dietary food computer operating procedures of MOHW. The applicant is required to fill out detailed information according to the following description in the columns highlighted in BLUE color.

1. 第一項英文品名，應以英文印刷體填寫，每個英文字母填一格，每個英文字間應空一格。

In the Table 1 "Product Name in English" shall be filled out in English and in block letter. Each box shall be filled out with an English letter, and a box shall be left blank between two English words.

2. 第四項成分其含量應填寫如下：

In the Table 4 "Ingredients", the content shall be filled out according to the followings:

例如: For examples:

Soyabeah oil	630.62	(kg/1000 kg)
Coconut oil	38.12	
Corn oil	27.93	
Calcium Hydroxide	2500.00	(g/1000 kg)
Ferrous Sulphate	310.00	

(每 1000 kg 中之成分含量) (content for every 1000 kg)

含 量										單 位	成 分 名 稱
Content										Unit	Name of Ingredient
6	3	0	6	2						2	Soyabeah oil
		3	8	1	2					2	Coconut oil
		2	7	1	2					2	Corn oil
2	5	0	0	0	0					3	Calcium Hydroxide
3	1	0	0	0	0					3	Ferrous Sulphate

↑  
→ 此線係小數點之分界線

The line is used to separate the decimal point.

特 殊 營 養 食 品 仿 單 標 籤 粘 貼 表 (一)

TABLE FOR PASTING OF INSTRUCTION MANUAL AND LABEL FOR SPECIAL  
DIETARY FOODS (I)

名 稱 Name		申請廠商 Applicant	
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