

特 殊 營 養 食 品 許 可 文 件 變 更 登 記 申 請 書

APPLICATION FORM FOR AMENDMENT OF PARTICULARS ON PERMIT DOCUMENT FOR SPECIAL DIETARY FOODS

受文者：衛生福利部

Recipient: Ministry of Health and Welfare

主 旨：本公司由「(原製造廠國別及名稱)」製造「(中文品名)」食品，擬申請變更「(例如：中文品名)」登記事項。

Subject: Application for amendment of 「(For example : Product name in Chinese)」 on permit document for the special dietary food (Original product name in Chinese) manufactured by (Country of origin and name of original manufacturer).

說 明：檢附之文件、資料如下(打☑記號者)：

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

☐一、基本文件、資料：Basic documents and information

☐（一）變更申請書乙份。 Application form for amendment, one copy.

☐（二）原許可文件正本。 Original copy of the permit document.

☐（三）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.

☐（四）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.

☐（五）變更登記資料表。List of the amendment of particulars on permit document.

☐二、依申請變更之項目，應另檢附之文件、資料或樣品如下：The following documents, information or sample shall be additionally submitted according to the application of amendment：

☐（一）產品名稱變更：Change of the product name

☐產品為輸入者，其原製造廠出具產品名稱變更之證明或同意文件正本乙份。

The original copy of the certificate or document of consent to change of the product name issued by the original manufacturer for imported products.

☐（二）許可文件持有廠商名稱、地址或負責人變更：Change of name, address or person-in-charge of the supplier holding the permit document：

☐1.許可文件持有廠商公司登記或商業登記證明文件影本乙份。Photocopy of company registration or business registration certificate of the supplier holding the permit document.

- ☐2.許可文件持有廠商之所有許可產品清冊乙份。A complete list of product items shown on the permit document held by the supplier.
- ☐ (三) 原製造廠名稱變更：Change of the original manufacturer's name
 - ☐1.國內製造者：工廠登記證明文件影本乙份。Domestic manufacturer: The applicant shall submit a photocopy of the manufacturer's factory registration certificate.
 - ☐2.國外製造者：出產國管理產品衛生安全或核發製造廠證照之政府機關最近二年內出具為合法工廠官方證明文件乙份。Foreign manufacturer: The original copy of the official certificate verifying the legitimacy of the original manufacturer issued by a competent government agency responsible for product hygiene and safety or factory licensing in the country of origin and dated within the past two years, shall be submitted.
 - ☐3.原製造廠之所有許可產品清冊乙份。A complete list of product items of the original manufacturer.
- ☐ (四) 原製造廠地址變更：Change of the original manufacturer's address
 - ☐1.國內製造者：工廠登記證明文件影本乙份。Domestic manufacturer: The applicant shall submit a photocopy of the manufacturer's factory registration certificate.
 - ☐2.國外製造者：出產國管理產品衛生安全或核發製造廠證照之政府機關最近二年內出具為合法工廠官方證明文件乙份。Foreign manufacturer: The original copy of the official certificate verifying the legitimacy of the original manufacturer issued by a competent government agency responsible for product hygiene and safety or factory licensing in the country of origin and dated within the past two years, shall be submitted.
 - ☐3.原製造廠之所有許可產品清冊乙份。A complete list of product items of the original manufacturer.
- ☐ (五) 包裝規格、型態、材質變更：Modification to the packaging specification, form and material：
 - ☐1.產品為輸入者，其原製造廠出具包裝變更之證明或同意文件正本乙份。For imported product items, the original manufacturer's certificate or document of consent to the change of packaging in original copy shall be submitted.
 - ☐2.型態或材質變更者，檢附樣品乙份。Product samples are required if changes involve form or material.

- ☐3.產品為**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乙份。The domestic repacking facility's factory registration certificate in photocopy.
 - ☐（3）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）分裝後樣品乙份(不同包裝規格、型態或材質者，應各別檢附之)。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.
- ☐（六）中文標籤、外盒包裝及說明書變更：Change of Chinese label, box packaging, and user instruction of the product：
- ☐1.產品為輸入者，檢附原製造廠出具中文標籤、外盒包裝及說明書變更之證明或同意文件正本乙份。For imported product items, the original manufacturer's certificate or document of consent to the change of Chinese label, box packaging, and user instruction in original copy shall be submitted.
 - ☐2.營養標示變更者，檢附原製造廠或中央主管機關認可之檢驗機構最近一年內出具之營養成分分析表正本乙份。For modification to the nutrition facts label, the original copy of the nutrients analysis report issued by the original manufacturer or an inspection body approved by the central competent authority within one year shall be submitted.

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)

LIST OF AMENDMENT OF PARTICULARS ON PERMIT DOCUMENT FOR SPECIAL DIETARY FOODS

原品名 Original Product Name

[illegible][illegible]

原申請商號 Original Applicant

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																				

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		<div> <div></div> <div></div> <div></div> <div></div> <div></div> </div>																											

三、製造廠 Manufacturer

原製造廠 Original Manufacturer

[illegible]

變 更 後 製 造 廠 Manufacturer after Amendment

分裝廠 Repacking Service Provider		名 稱 Name																																	
		地 址 Address																																	
製造廠 Manu- facturer	名 稱 Name																																		
	地 址 Address																																		

四、外觀 (請以下列代碼填入): Appearance (Please fill out following table using the Arabic number below)

(A) 劑 型 Product Form : 05.粉劑 Powder 12.液劑 Liquid

(B) 包裝材料 Packaging Material : 01.塑膠袋 Plastic Bag 02.塑膠瓶 Plastic Bottle 03.塑膠桶 Plastic Bucket 04.鋁桶 Aluminum Bucket 05.鋁罐 Aluminum Can 06.鐵桶 Iron Bucket 07.鐵罐 Iron Can 08.馬口鐵桶 Tin Bucket 09.紙盒 Paper box 10.紙袋 Paper Bag 11.紙箱 Cardboard Box 12.紙桶 Fiber Drum 13.玻璃瓶 Glass Bottle 14.鋁箔紙 Aluminum Foil 15.無 N/A 16.紙罐 Paper Can 17.鐵盒 Iron Box 18.塑膠罐 Plastic Jar 19.塑膠盒 Plastic Box

(C) 包裝單位 Packing Unit : 01.公克 Gram 02.公斤 Kilogram 13.毫升 Milliliter 14.盎司 Ounce

原外觀 Original Appearance

[illegible]

