

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) 變更涉及產品中文標籤、容器或外包裝及說明書者，其實體或彩色擬稿各二份；其包裝規格、型態、材質不同者，分別檢附之；說明書內容相同者，得檢送任一規格、型態、材質者之說明書。 Two copies each of the physical or color drafts of the Chinese labels, container or outer packaging, and user instructions of the product that are involved in amendment; the above items shall be attached separately for different packaging specifications, forms, and materials; if the contents of the user instructions are the same, the user instructions of any specifications, forms, and materials may be submitted.

(四) 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 manufacturer 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 manufacturer 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 manufacturer.
- (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: Carbon copy of the 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，以全銜出具，並載明製造廠名稱、地址、營業項目、產品種類、工廠之衛生狀況，經該政府機關或其主管官員戳記或簽章；其為影本者，經原產國公證單位簽證與正本相符。Foreign manufacturer: The original official certificate 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 provided. The certificate shall specify the name and address of the manufacturer, its business activities, categories of products, hygienic status of the factory, and full name of the government agency issuing the certificate with official stamp or authorized signature. If the certificate verifying the legitimacy of the original manufacturer is a copy of the original, the document shall be a certified true copy of the original by a notary public in the country of origin.
 - 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) 原製造廠門牌整編：Building number adjustment of the original manufacturer's address
 - 1. 國內製造者：政府機關出具，足資證明門牌整編之文件影本乙份。In cases of domestic manufacturers: The applicant shall submit a photocopy of the documents issued by a competent government agency certifying the address building number adjustment.
 - 2. 國外製造者：出產國政府機關已全銜出具，足資證明門牌整編之文件；其為影本者，經原產國公證單位簽證與正本相符。In cases of foreign manufacturers: The original certificate issued by a competent government agency of the country of origin in its full title certifying the building number adjustment, whereas the certificate submitted is a photocopy, the document shall be notarized as a true copy of the original by a notary public in the country of origin.

- 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) 產品規格變更：Amendment of the product specifications:
 - 1. 原製造廠最近一年內出具之變更合理性評估報告，包括變更內容前後對照表。The evaluation report on the rationale of amendment issued by the original manufacturer within the past one year (including a chart of comparison of the content before and after the amendment).
 - 2. 第十三條或第二十條第一項第一款及第二款規定之文件，並依變更之規格項目，檢附同條項第三款規定之文件。The documents set forth in Article 13 or 20, Paragraph 1, Subparagraphs 1 and 2, attaching those set forth in Subparagraph 3 of the same Article and Paragraph, based on the amended items of specifications.
- (六) 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.產品為須**再分裝**者，並檢附下列文件及樣品：Where the product is intended to 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 re-packing certificate or document of consent to product re-packing 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 re-packing facility's factory registration certificate in carbon copy.
 - (3) 原製造廠或中央主管機關認證之食品檢驗機構最近一年內出具之分裝產品衛生及營養成分分析表正本乙份。The original copy of the hygiene and nutrition analysis report on the re-packed product issued within the past one year by the original manufacturer or accreditation of food testing institution by the central competent authority.
 - (4) 分裝產品中文標籤、容器或外包裝及說明書之實體或彩色擬稿各二份；其包裝規格、型態、材質不同者，分別檢附之；說明書內容相同者，得檢送任一規格、型態、材質者之說明書。Two copies each of the physical or color drafts of the Chinese label, container or outer packaging, and user instructions of the re-packed products; the above items shall be attached separately for different packaging

specifications, forms, and materials; if the contents of the user instructions are the same, the user instruction of any specification, form, and materials may be submitted.

(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.

(七) 中文標籤、容器或外包裝及說明書變更： Change of Chinese label, container or outer packaging, and user instruction of the product：

1. 產品前後對照表。A chart of comparison of the content before and after the amendment.

2. 產品為輸入者，檢附原製造廠出具中文標籤、容器或外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, container or outer packaging, and user instruction in original copy shall be submitted.

3. 營養標示變更者，檢附原製造廠最近一年內出具之變更合理性評估報告、產品成分含量表正本及產品規格表正本；原製造廠或中央主管機關認證之食品檢驗機構最近一年內出具之營養成分分析表正本。For amendment to the nutrition facts label (with no changes of the product ingredients and content): The evaluation report on the rationale of amendment issued by the original manufacturer within the past one year and original table of ingredient content and original product specification; The original copy of the nutrition analysis report issued by the original manufacturer or accreditation of food testing institution by the central competent authority within the past one year.

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)

三、製造廠 Manufacturer

原製造廠 Original Manufacturer

分裝廠 Repacking Service Provider	名稱 Name																														
	地址 Address	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>																													
製造廠 Manu- facturer	名稱 Name																														
	地址 Address																														

變更後製造廠 Manufacturer after Amendment

分裝廠 Repacking Service Provider	名稱 Name																														
	地址 Address	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>																													
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.其他 Others 16.無 N/A 17.紙罐 Paper Can 18.鐵盒 Iron Box 19.塑膠罐 Plastic Jar 20.塑膠盒 Plastic Box 21.保麗龍盒 Styrofoam box 22.麻布袋 Burlap Bag 23.錫箔紙 Tin Foil 24.鋁箔片 Aluminum Foil Sheet 25.槽車 Tank Car 26.錫罐 Tin Can 27.鋁箔袋 Aluminum Foil Bag 28.泡殼包裝 Blister Packing 29.PP 編織袋 PP Woven Bag 30.紙布複合袋內襯塑膠膜 Paper-cloth Composite Bag with plastic lining 31.無錫罐 Tin-Free Steel Can 32.尼龍 編織袋 Woven Nylon Bag 33.馬口鐵罐 Tin Can 34.不銹鋼櫃 Stainless Steel Cabinet 35.塑膠片 Plastic Sheet 36.不鏽鋼桶 Stainless Steel Bucket 37.鋁箔包 Tetra Pak 38.塑編袋 Plastic Woven Bag 39.編織袋 Woven Bag 40.紙塑複合袋 Paper-plastic Composite Bag
- (C) 包裝單位 Packing Unit : 01.公克 Gram 02.公斤 Kilogram 13.毫升 Milliliter 14.盎司 Ounce

