

**特殊營養食品許可文件展延登記申請書**  
**APPLICATION FORM FOR EXTENSION OF PERMIT DOCUMENT**  
**FOR SPECIAL DIETARY FOODS**

受文者：衛生福利部 Recipient: Ministry of Health and Welfare (MOHW)

主 旨：本公司由「(原製造廠國別及名稱)」製造「(中文品名)」食品一種，擬申請展延貴  
部 年 月 日部(衛)授食字第 號許可文件有效期限。

Subject: Application for extension of the permit document (Bu (Wei)-Shu Shih-Tze No. \_\_\_\_\_) issued by MOHW on \_\_\_\_\_(Date) for (Product Name in Chinese) manufactured by (Country of origin and name of original manufacturer).

說 明：檢附之文件、資料及產品如下(打☑記號者)：

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

- ☐ (一)展延申請書乙份。Application form for extension, one copy.
- ☐ (二)原許可文件正本。Original copy of the permit document.
- ☐ (三)原製造廠最近一年內出具依原許可內容繼續製造之證明或同意文件正本，或產品原料成分含量表正本乙份。The original copy of the certificate or document of consent to renewal of the product manufacturing agreement, or original copy of the product ingredient list issued by the original manufacturer based on the content of originally issued permit within one year.
- ☐ (四)委託製造者，其委託證明文件正本乙份。A contract manufacturer is required to provide the original copy of the manufacturing contract.
- ☐ (五)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.
- ☐ (六)市售產品乙份。One sample of the off-the-self product.
- ☐ (七)申請嬰兒與較大嬰兒配方食品者，應檢附國外之販售證明及產品，或有效樣本數二十人以上之試用報告。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.
- ☐ (八)申請特定疾病配方食品者，應檢附營養成分分析表正本乙份。For Formula for certain disease, the original copy of the nutrients analysis report shall be

submitted.

- ☐ (九)申請**特定疾病配方食品**者，應檢附臨床人體食用研究報告乙份(屬營養均衡完整配方者免附)。Clinical study report for the product under application, one copy (applications for nutritionally complete food with balanced formula is exempted from the requirement).

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 )