

# 特殊營養食品查驗登記申請書

## APPLICATION FORM FOR REGISTRATION OF SPECIAL DIETARY FOODS

### ( 特 定 疾 病 配 方 食 品 查 驗 登 記 - 提 會 審 查 )

### ( APPLICATION FORM FOR REGISTRATION OF FORMULA FOR CERTAIN DISEASE-MEETING REVIEW)

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)

- ☐ 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：本次新增或更新之資料如下(請勾選)：

Description: The new or updated information is as follows(ticked items)

- ☐ (一) 申請書表乙份。Application form, one copy.
- ☐ (二) 產品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) 製程作業重點資料乙份。Manufacturing process summary, one copy.
- ☐ (五) 產品中文標籤、容器及外包裝及說明書之實體或彩色擬稿各乙份。One copy each of the physical or color drafts of the Chinese label, container or outer packaging, and user instructions of the product.

(六) 申請類別為營養調整完整配方食品、營養調整補充配方食品或特殊單素配方食品者，應另檢附下列文件、資料：Applicants for nutritionally complete food with customized formula, nutrition adjusted supplementary formula food, or special modular formula food, 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(六)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.

☐ (七) 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.

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

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

備 註：

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 )