健康食品查驗登記申請書表
(個案審查)-初審

APPLICATION FORM FOR REGISTRATION OF HEALTH FOOD
(Case Review)-Preliminary Review

品　　名
Product Name :

申　請　廠　商
Applicant :

聯　絡　人
Contact Person :

聯絡人電話
Telephone No. :

聯絡人電子郵件
Contact E-mail :

本申請案均已審慎確認文件資料正確性。

The accuracy of the documents and information for this application has been duly affirmed.

中華民國　　年　　月　　日

Date: _____

填 表 須 知

Instructions

一、一般注意事項 General Notifications

(一) 健康食品查驗登記申請書表請由網際網路下載使用，下載之申請書表如不敷使用，請依本部所訂格式自行複製，自行複製之書表應於標題後面加註編號，例如：健康食品查驗登記資料(一)、(二)、(三)、(四)。

Please download the Application Form for Health Food Registration from the internet. If there isn't enough space on the downloaded application form, please make copies of the forms and each with the same format. Each copy shall have a number after the title, for example: Health Food Registration Information (1), (2), (3), (4).

(二) 申請書表應以電腦鍵入相關資料列印之（軟體：**Microsoft Word**；字體標楷體，字體大小可視實際需要加以調整），並以活頁方式裝訂成冊。送審時應檢附儲存有前述檔案之光碟片，以利審查作業之進行。

The application form shall be typewritten using a computer and printed out (Software: Microsoft Word; Font: DFKai-SB; Size: subject to adjustment as needed), and bound with loose-leaf binders. A disc containing the foregoing file shall be included in the submittal to facilitate the review procedure.

(三) 檢送之書件、資料、文獻，應以 **A4** 紙張（**210 mm×297 mm**）製作；如大於 **A4**，請摺疊成 **A4** 大小，並請依序排列，檢附於附件處，且編訂頁碼及附件側標籤，以利審查。

The documents, information, and literature shall be printed on A4-size (210mm × 297mm) papers; if the papers are larger than A4 size, please fold them into the size of A4, place them in order as attachments, and insert the page number to facilitate the review procedure.

(四) 書件、資料、文獻之摘要表、一覽表內記載之資料編號順序，應與所檢附附件（書件、資料、文獻）之序號相同。

The numbering sequence of documents, information, literature summary table, and overall list shall correspond to that of the annexed attachments (documents, information, literature).

(五) 檢送之書件、資料、文獻，如以非英文之外文撰寫者，應另檢附一份經政府立案翻譯社翻譯之中譯本。簡體中文者，應另檢附一份繁體中文本，得自行翻譯。

If the submitted documents, information, literature are not in English, please submit a Chinese version translated by a government-accredited translation service company. Those in simplified Chinese shall be submitted with a traditional Chinese version which can be translated by applicant.

(六) 檢送各項之評估或檢驗報告應為正本，且試驗產品應與申請產品（最終產品）相同，其評估報告應有試驗計畫主持人及試驗執行人簽名。

The assessment or test reports submitted in the attachment should be the original copies, and the product for which a new application has been made, namely the final product, and the originally-tested product shall be identical. The assessment reports shall be

signed by the principal investigator and the test executor for future reference.

(七) 評估試驗報告應為申請案專案撰寫之報告，其報告撰寫（如格式、單位、大小寫）應參考科學文獻規範。

The assessment report shall be a tailored report for the application. Report writing (such as format, unit, case) shall conform to scientific literature writing standards.

(八) 倘試驗執行機構單位之試驗項目通過認證或查核，或實驗室具符合優良操作規範等認證者，得檢附相關證明文件影本。

Certificates and documents certifying that the institution that conducts the test is approved/examined, or the certificates certifying that the laboratory meets the requirements of good laboratory practices could be attached.

(九) 所提國內外同類產品之研究應用資料，包括佐證產品安全性、功效性、安定性及檢驗方法等，其文獻應符合一般學術倫理規範。

The research reports and literature of similar domestic and foreign are provided to support the safety, efficacy, stability of the product and clarify the inspection methods. The literature shall conform to the general ethical standard for academic work.

(十) 申請案所執行之各項評估試驗，應符合現行評估方法規定；倘為評估方法公告修正前所執行之試驗，除另有規定外，執行試驗時間應為公告修正生效日起 2 年內。

The assessment of the execution of the application shall comply with the requirements of the current assessment method. If the assessment is carried out before the revision of the assessment method, unless otherwise announced, shall have been performed within two years after the effective date of the current regulations.

(十一) 依「健康食品查驗登記食品化學檢驗方法審核查檢表」及「健康食品查驗登記功效微生物檢驗方法審核查檢表」檢附「檢驗方法標準作業程序文件」供審。

In accordance with the “Review Form of Chemical Inspection Method for Health Food Registration” and “Review Form of Microbial Inspection Method for Health Food Registration”, the submission should include the "Standard Operating Procedure Document for Inspection Methods" for the purpose of review.

(十二) 申請商應審慎確認所檢具相關文件及資料無誤；倘本須知尚有其他未盡事宜，應以健康食品管理法及健康食品申請許可辦法為準。

The applicant shall prudently ensure the correctness and authenticity of the documents and information attached. For any matters not covered in this instructions, the Health Food Control Act and the Regulations for Application of Health Food Permit shall prevail.

二、填表說明

Instructions for Completing the Form

(一) 申請廠商基本資料：

Basic Information of the Applicant：

1. 申辦「輸入」健康食品查驗登記者，製造廠欄位之負責人、工廠登記證編號、統一編號等免填。

An applicant applying for registration of "imported" health food is not required to fill out the fields of the responsible person of the manufacturer, factory registration number, and unified business number.

2.產品如係「委託製造」，應填明「委託製造者」欄位之相關資料，並檢附經委託者及受委託者雙方簽署之委託製造合約書正本乙份，且合約書中應載明申請案之產品、申請商及委託製造廠，及合約應於有效期限內。

Where products are manufactured by a contract manufacturer, please fill out the "Contract Manufacturer" field and attach an original copy of the contract manufacturing agreement signed by the contracting parties.

3.健康食品查驗登記資料**(**一**)**、**(**二**)**、**(**三**)**、**(**四**)**：

Health Food Registration Information (1) (2) (3) (4)

(1)健康食品查驗登記資料**(**一**)**

Health Food Registration Information (1)

A.品名不得有仿冒或影射他人已註冊商標之情事。

The product name shall not counterfeit or allude to the registered trademarks of others.

B.原料成分之含量應包括所有原料及食品添加物之詳細名稱（中英文並列）及含量；依其含量多寡由高往低列出，含量單位以重量百分比表示。原料之名稱應使用一般通用名稱，不得使用商品名。

The ingredient content information shall include the names of all ingredients and food additives (in both Chinese and English) and the content shall be listed in order from the highest percentage by weight to the lowest percent by weight. The names of the ingredients shall be the generic names instead of trade names.

(2)健康食品查驗登記資料**(**二**)**

Health Food Registration Information (2)

A.保健功效敘述及其原料成分欄，應列出保健功效內容，並於該內容之後，依保健功效作用之大小為序，標明「保健功效成分（原料）」；若同時申請一種以上之保健功效，則應逐一列出。

In the field of "health care effect and the ingredient content", descriptions of the health care effect shall be provided and after which, the "content (ingredient) with health care effect" shall be specified in the order of degree of efficacy of the health care effect. If more than one type of health care effect is being applied, each type of healthcare effect shall be listed.

B.填寫之食用方法（攝取量、注意事項、警語）、保存方式（保存方法、條件、期間）、保健功效敘述等項應與評估、試驗報告結果相符。

The usage instructions (amount of intake, precaution and warning), preservation method (storage method, storage condition and shelf life), health care effect descriptions shall match those of the assessment and testing reports.

(3)健康食品查驗登記資料**(**三**)**

Health Food Registration Information (3)

A.食品外觀形態，應載明如液狀、粉狀、錠狀或膠囊狀……等。

The appearance of the food shall be clearly stated as liquid, powder, tablet, capsule, etc.

B.包裝（材質、重量容量）欄位，應載明所有包裝種類；材質應載明內、外包裝材料。材質與重量容量之編號應相互對應。

In the field of packaging (material, weight capacity), all types of packaging shall be clearly stated; materials shall be marked as for inside and outer packaging. The numbering of material shall correspond to that of weight capacity.

(4)健康食品查驗登記資料**(**四**)**：申請查驗登記之緣由欄位，應具體填明產品具有保健功效之理由。

Health Food Registration Information (4) The field of "application reason(s)" shall clearly state the reason(s) why the product has health care effect.

(二**)** 產品原料成分規格含量表：

Specifications and Quantity of Ingredients：

1.原料成分之含量應包括所有原料及食品添加物之詳細名稱（中英文並列）及含量；依其含量多寡由高往低列出，含量單位以重量百分比表示。

The ingredient content information shall include the names of all ingredients and food additives (in both Chinese and English) and the content shall be listed in order from the highest percentage by weight to the lowest percent by weight.

2.原料成分規格含量表應為製造廠所出具，且包括保健功效成分之規格；其正本檢附於附件處。

The table of the specifications and content of materials shall be issued by the manufacturer and indicate the specifications of ingredients with health care effect, and the original copy shall be annexed as attachment.

3.所有原料應含供貨來源、供貨規格（含原料之品管及衛生檢驗）及驗收報告；所附之相關報告應並包括執行人與核准人之簽章及日期。

Sources and specifications of all ingredients (including quality control and sanitation testing of the ingredients) and inspection reports shall be included. The attached report shall have the signature and date of the executor and the approver.

4.原料為經萃取或濃縮者，應另檢附製程、萃取溶劑、溶媒及濃縮方法與倍數。

For extracted or concentrated raw materials, information on the process, extraction solvent, concentration method, and concentration times of extracted or concentrated shall be attached.

5.原料為食品添加物者，應另檢附食品添加物許可證影本；屬複方食品添加物者，應含展開之配方說明。

In the case of food additives, copies of food additive registration license shall be attached, in the case of compound food additives, the formula shall be indicated and instructed.

6.產品外觀型態為膠囊狀者，應另檢附該空膠囊殼配方。

For products in capsules, the formula description of the capsule shell should be attached.

7.保健功效成分原料為外購者，應另檢附檢驗報告、製程及合法工廠文件影本。

If raw materials are purchased from foreign countries, test reports, manufacture process and certificates of legal factory shall be submitted.

8.原料含菌株者，應另檢附購菌或菌株來源證明及菌種鑑定報告；另原料含乳酸菌者，應另檢附菌株鑑定報告。

In case of raw materials containing strain, certificates of origin or microorganism evaluation reports of all strains shall be submitted, for materials containing lactic acid bacteria, the strain identification report should be attached.

9.原料含可供食品用之中藥材者，應另檢附基原鑑定報告。

In the case of edible Chinese medicines, medicinal plant assessment reports shall be submitted.

(三) 產品之安全評估報告摘要表：

Summary Table of Safety Assessment Report

1.將學術研究機構出具之安全評估報告摘錄於本表，其正本檢附於附件處。

The product safety assessment report issued by an academic institution shall be summarized and included in the form and the original copy shall be annexed as attachment.

2.安全性為第一類之產品，應檢附相關文獻並含中文說明、重點劃線及側標籤。

The product for which a new application has been made and the originally tested product shall be identical.

3.安全性為第二類以上之產品，應依健康食品安全性評估方法規定檢附相關報告。

For products with a safety category of 2 or higher, relevant reports shall be attached in accordance with the health food safety assessment method.

4.安全評估報告應含清晰之彩色組織切片圖，且所附之組織病理檢驗報告應含獸醫師或醫師進行判讀並簽名。

Safety assessment report shall contain clear and colored photo of tissue slices, and be signed by veterinarians or physicians with animal pathology background for future reference.

5.倘安全評估方法與公告方法有所不同(如測定方法)時，應另檢附其科學性依據說明或資料。

If the safety assessment method used in the test report is slightly different from the method announced by the FDA (such as the measurement method), the scientific basis of the method shall be attached for the assessment.

6.安全評估報告應檢附所有試驗個體之完整數據以供驗證，且分析之樣本應為固定受試個體，不得任意刪除數據，並應使用適當之統計方法分析實驗數據。

Safety assessment report shall contain complete data of all test subjects for verification, and the samples in the assessment report shall be fixed subjects, and the data shall not be deleted arbitrarily. Appropriate statistical methods shall be used to analyze the experimental data.

7.以動物實驗執行應另檢附實驗動物照護及使用委員會或小組同意書；如試驗計畫主持人與試驗執行人不同時，應另檢附試驗執行機構之實驗動物照護及使用委員會或小組同意書。

In the case of animal testing, a written consent from the Institutional Animal Care and

Use Committee shall be provided. In case the principal investigator and the test executor are different, a written consent from the Institutional Animal Care and Use Committee of the executing institution shall be attached.

8.倘產品成分含新穎性食品原料或物質者，須由不同於該食品原料或物質之研發單位出具相關安全評估報告。

If the ingredients or raw materials used in the application products are novel, the health care effect assessment report shall not be published by the institutions that develop the same ingredients or raw materials.

(四) 產品之保健功效評估報告摘要表：

Summary Table of Health Care Effect Assessment Report：

1.將學術研究機構出具之保健功效評估報告摘錄於本表；其正本檢附於附件處。

The health care effect assessment report issued by an academic institution shall be summarized and included in the form and the original copy shall be annexed as attachment.

2.功效評估報告以已發表於學術期刊者為佳；倘為未經發表者，應為具公信力試驗機構或單位完成之報告；倘為申請者本身試驗機構或單位出具者，應列舉其本身具有相當之專業研究能力及公正性之佐證資料。

Health care effect assessment report that is published in academic journals are preferred；if the report issued by a testing institution or entity of the applicant itself should have the credentials as evidence of its considerable professional research capabilities and impartiality.

3.倘試驗以人體食用研究或動物實驗執行者，應另檢附人體實驗倫理委員會同意書或實驗動物照護及使用委員會或小組同意書、受試者志願書、受試者篩檢表、飲食指導書及每日飲食追蹤紀錄等資料，如動物試驗計畫主持人與試驗執行人不同時，應另檢附試驗執行機構之實驗動物照護及使用委員會或小組同意書；惟動物實驗之有效劑量與人體建議攝取量不同時，應另檢附相關佐證文獻。

If human subject research or animal testing used in the health care effect assessment test, Consent form the Human Research Ethics Review Board, proposal or a written consent from the Institutional Animal Care and Use Committee, consent from the subjects, screening conditions, diet instruction and diet record shall be submitted. When the principal investigator and the test executor are different in animal testing, a written consent from the Institutional Animal Care and Use Committee of the executing institution shall be provided. If the effective dose of animal experiment is different from that of recommended intake for humans, relevant literature shall be further provided.

4.功效評估報告應含清晰之彩色組織切片圖，且所附之組織病理檢驗報告應含獸醫師或醫師進行判讀並簽名。

Health care effect assessment report shall contain clear and colored photo of tissue slices, and be signed by veterinarians or physicians with animal pathology background for future reference.

5.倘功效評估方法與公告方法略有不同(如測定方法)時,應另檢附其科學性依據說明或資料。

If the health care effect assessment method used in the test report is slightly different from the method announced by the FDA (such as the measurement method), the scientific basis of the method shall be attached.

6.功效評估報告應檢附所有試驗個體之完整數據以供驗證,且分析之樣本應為固定試驗個體,不得任意刪除數據,並應使用適當之統計方法分析實驗數據。

The attached effect assessment report shall contain complete data of all test subjects for verification, samples in the assessment report shall be fixed subjects and the data shall not be deleted arbitrarily. Appropriate statistical methods shall be used to analyze the experimental data.

7.倘產品成分含新穎性食品原料或物質者,須由不同於該食品原料或物質之研發單位出具相關功效評估報告。

If the ingredients or raw materials used in the application products are novel, the health care effect assessment report or the health care effect assessment report shall not be published by the institutions that develop the same ingredients or raw materials.

(五) 產品之保健功效成分鑑定報告摘要表:

Summary Table of the Identification Report on Ingredients with Health Care Effect of a Product:

1.將製造廠或委託其他檢驗機構所提具之鑑定報告,摘錄於本表;其正本檢附於附件處。

The identification report issued by the manufacturer or another inspection body shall be summarized and included in the form and the original report shall be annexed as attachment.

2.鑑定報告應包括工廠生產線產製之三批產品保健功效成分或規格成分之定性及定量試驗結果,其中至少二批檢驗完成日期應於三年內。

The identification report shall include the qualitative and quantitative test results of three batches of product ingredients or specification ingredients produced by factory production line, of which at least two batches should have the inspection completed within the past three years.

3.鑑定報告之檢驗方法應為國內公告或建議檢驗方法或國際間公認之方法,且應另檢附其檢驗方法標準作業程序及確效等相關資料,並依「健康食品查驗登記食品化學檢驗方法審核查檢表」及「健康食品查驗登記微生物檢驗方法審核查檢表」所載內容為之;採其他檢驗方法者,應檢附參考文獻及方法比對資料。

The identification report methods shall be generally recognized domestically or internationally, with relevant information such as validation and "Standard Operating Procedure Document for Inspection Method "shall be attached, and follow the "Review Form of Chemical Inspection Method for Health Food Registration" and "Review Form of Microbial Inspection Method for Health Food Registration". If other test method is adopted, literature and comparison shall be attached to support.

4.現有技術無法確定有效保健功效成分者,應另檢附具該保健功效之各項原料或佐證文獻。

In case existing technologies cannot determine ingredients with health care effect, other

raw materials with the health care effect or supporting literatures shall be attached.

(六) 產品之安定性試驗報告摘要表：

Summary Table of Test Report on the ingredient stability of a product and its health care effect：

1.將製造廠提具之安定性試驗報告（包括試驗方法、數據、結果）摘錄於本表；其正本檢附於附件處。

The stability test report (including testing method, data and results) issued by the manufacturer shall be summarized and included in the form and the original copy shall be annexed as attachment.

2.安定性試驗報告應包括計畫書及工廠生產線產製之三批試驗結果，其中至少二批檢驗完成日期應於三年內，並檢附保健功效成分鑑定檢驗方法之確效等相關資料。

Test report on the ingredient stability of a product shall be submitted proposals and three batches result manufactured by the factory production line, of which at least two batches of inspection shall be completed within three years, and ingredients with health care effect of relevant information such as the validation shall be annexed as attachment.

3.倘產品為膠囊或錠狀者，應另檢附崩散性試驗項目，且膠囊狀產品尚應再檢附脆裂度試驗項目。

Products in capsules or tablet forms shall be subject to disintegration test. Capsules shall also be subject to brittleness test.

(七) 產品製程概要：

Summary of Manufacturing Process：

1.將製造廠提具之產品製程概要（包括原料調理、加工流程及加工條件）摘錄於本表；其正本檢附於附件處。

The documents substantiating the manufacturing and processing process issued (including ingredient preparation, manufacturing process ,and processing conditions) by the manufacturer shall be summarized and included in the form, and the original report shall be annexed as attachment.

2.製造加工流程應以具體完整之流程圖表示（包括原料調理），並應加註明確之加工條件。

The manufacturing and processing process shall be completely illustrated in a flow chart (including ingredient preparation); moreover, the processing conditions shall be clearly indicated.

3.經萃取者，應另說明萃取方法及其溶劑；經濃縮者，應另說明濃縮之倍數。

Those being extracted shall explain the extraction method and the solvents used. Those being concentrated shall be provided the concentration factor.

(八) 良好作業規範之證明資料摘要表：

Summary Table of Documentary Evidence of Good Manufacturing Practices：

1.健康食品為國產者：

If an applicant apply for domestically produced：

(1)將符合中央主管機關所定良好作業規範所規定製作之相關製程管制資料 (如程序書、產

品之製程管制文件、品質管制文件及品管工程圖或等同之文件)摘錄於本表；其正本檢附於附件處。

The information on control of the manufacturing process (such as procedures, manufacturing process control documents, quality control documents, and quality control engineering drawings or equivalent documents) in accordance with the good manufacturing practices regulations enacted by the central competent authority shall be summarized in the application table, with the original copy submitted in the attachment.

(2)倘製造廠係藥廠兼製者，應另檢附藥廠得兼製食品之證明文件；如為不同生產廠房，則應再檢附廠區平面圖佐證。

If the health foods are manufactured along with other medications, a certificate proving that the factory can manufacture both drug and food products shall be submitted. If health food and medicine are produced in different production plants, the factory floor plan shall be attached as evidence

2.健康食品為輸入者：將原產國良好作業規範之法規全文、品管計畫書及符合原產國之良好作業規範之證明文件正本，檢附於附件處。

An applicant applying for "imported" health food registration shall include in the form the summary of the official document evidence the good manufacturing practices presented by the original manufacturer and annex the original evidence document, the full text of the Good Manufacturing Practices of the country of origin, quality management plan as attachment.

3.倘製造廠具其他品管系統認證者，得另檢具相關證明文件影本佐證其具執行之能力。

If the manufacturer has certificates issued by other quality control system, it may submit the copy of relevant documents to prove that it has the ability to implement the good manufacturing practices for health food

4.倘產品製程係經二間（含）以上製造廠「分段製造」者，應另檢附不同製造廠出具個別之符合中央主管機關所定良好作業規範所規定之相關文件資料。

If two or more manufacturing plants are involved in the manufacture process, documents regarding the good manufacturing practices followed by the central competent authority of each manufacturing plant shall be submitted respectively.

(九) 產品衛生檢驗規格及其檢驗報告摘要表：

Summary Table of Sanitary Specifications and its Test Report：

1.將製造廠或委託其他檢驗機構所提具之檢驗報告，摘錄於本表；其正本檢附於附件處。

The analysis report issued by the manufacturer or another inspection body shall be summarized and included in the form and the original report shall be annexed as attachment.

2.檢驗報告應為工廠生產線產製之三批產品之檢驗結果，其中至少二批檢驗完成日期應於三年內；另檢驗報告應包括檢驗方法清單。

The report shall include the test results of three batches of products produced in factory line, of which at least two batches of inspection shall be completed within three years.

3.檢驗報告應包括健康食品衛生標準所規定之檢驗項目。

The contents of the report shall comply with the sanitation standards of health food.

(十) 一般營養成分分析報告摘要表：

Summary Table of General Nutrients Analysis Report：

1.將製造廠或委託其他檢驗機構代驗者所提具之分析報告摘錄於本表；其正本檢附於附件處。

The analysis report issued by the manufacturer or another inspection body shall be summarized and included in the form and the original report shall be annexed as attachment.

2.分析報告應為工廠生產線產製之三批產品之檢驗結果，其中至少二批檢驗完成日期應在三年內；另分析報告應包括檢驗方法清單。

The general nutrients analysis report shall include the test results of three batches of products produced in factory line, of which at least two batches of inspection shall be completed within three years.

3.分析報告應含包裝食品營養標示應遵行事項所規定之熱量及營養素項目，且應註明營養成分單位，及每一份量營養成分換算方式之說明。

The general nutrients analysis report shall include the calories and nutrient items followed by the Regulations on Nutrition Labeling for Prepackaged Food Products, and the unit measuring the nutrients shall be specified with the conversion method of each serving specified.

4.倘產品屬膠囊者，應另含膠囊殼之檢驗結果。

For products in capsules, the test results of the capsule shell should be presented.

(十一) 相關研究報告文獻資料一覽表：

Overall List of Relevant Research Reports and Literatures：

1.將相關研究報告文獻資料摘錄於本表；其全文檢附於附件處。

The relevant research report and literation information shall be summarized and included in the form and the full text shall be annexed as attachment.

2.檢附之文獻應另有中文說明、重點劃線及側標籤。

Chinese description, underline and index labels shall be included in literature.

(十二) 產品包裝、標籤及說明書(一)、(二)、(三)：

Product Package, Label and Information Leaflet (1), (2), (3)：

1.產品包裝、標籤及說明書(一)、(二)：

Product Package, Label and Information Leaflet (1), (2)：

(1)將產品中文標示內容填入表格內之「產品標示內容」欄位。

Fit the content of the Chinese labels according to Product Label Content.

(2)填入之內容應符合健康食品管理法及健康食品應加標示事項規定。

The content shall be in accordance with “Health Food Control Act” and “Regulations Governing the Labeling of Health Food”.

2.產品包裝、標籤及說明書(三)：

Product Package, Label and Information Leaflet (3)：

(1)將產品包裝、標籤、說明書浮貼於表格內。

Paste the package, label, information leaflet onto (3).

(2)浮貼之標籤及說明書以全型實物為原則，並為彩色列印且為實際大小等比例輸出清晰可辨識之文字，並可摺疊浮貼於書冊；倘其因實物過大或因包材之因素致不便浮貼時，得以實物之彩色照片替代之。

In principle, the label and information leaflet pasted shall be the real ones used by the company. Where pasting is not possible due to the oversize problem or packing material factor, the color photos of the actual package may be pasted onto the table as an alternative.

(十三) 公司登記或商業登記之證明文件影本粘貼表：將公司證明文件影本浮貼於表格內。

Table for Pasting of the Copy of Registration Certificate of the Applicant's Corporation or Business：Paste the copy of business registration certificate or document onto the form.

目次 Table of Content

項　　目 Item **頁數 Page**

一、 製造（輸入）健康食品查驗登記個案審查初審申請書
Application Form of Preliminary Case Review for Registration of Produced (Imported) Health Food ・・・

附　　件 **Attachments**：

1. 委託製造合約書正本（非屬委託製造者，本項應留空）
   Original Copy of the Contract Manufacturing Agreement (Ignore if it's not an OEM contract)・・・・・・・・・・・・・・・・・・・・・・・・・・・・・（　　）
2. 製造廠出具之產品原料成分規格含量表正本
   Original Copy of Specifications and Quantity of Ingredients issued by the Manufacturer・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・（　　）
3. 產品之安全評估報告正本
   Original Copy of Safety Assessment Report・・・・・・・・・・・・・・・・・・（　　）
4. 產品之保健功效評估報告正本
   Original Copy of Health Care Effect Assessment Report・・・・・・・・・・・・・・（　　）
5. 保健功效成分鑑定報告正本、其檢驗方法標準作業程序及確效資料
   Original Copy of Identification Report on Ingredients with Health Care Effect of a Product, its Inspection Method Employed and Standard Operating Procedure for Inspection Methods・・・・・・・・・・・・・・・・（　　）
6. 保健功效安定性試驗報告正本
   Original Copy of Test Report on the Ingredient Stability of a Product and its Health Care Effect・・・・・・・・・・・・・・・・・・・・・・・・・・・・・（　　）
7. 製造廠出具之產品製程概要資料正本
   Original Copy of Summary of Manufacturing Process・・・・・・・・・・・・・・（　　）
8. 良好作業規範之證明資料正本
   Original Copy of Documentary Evidence of Good Manufacturing Practices・・・・（　　）
9. 產品衛生檢驗規格及其檢驗報告正本
   Original Copy of Sanitary Specifications and its Test Report・・・・・・・・・・・（　　）
10. 一般營養成分分析報告正本
    Original Copy of General Nutrients Analysis Report・・・・・・・・・・・・・・（　　）
11. 相關研究報告文獻資料
    Relevant Research Reports and Literatures・・・・・・・・・・・・・・・・・・（　　）

製造（輸入）健康食品查驗登記個案審查初審申請書

Application Form of Preliminary Case Review for Registration of Produced (Imported) Health Food

受文者：衛生福利部
Recipient : Ministry of Health and Welfare
主　旨：本公司擬□製造□輸入「中文品名：　　」食品乙種，申請查驗登記。
Subject : The company intends to □produce □import _____ (Product Name), and files an application for registration.
說　明：檢附之書件、資料如下:
Description: The attached documents and information include:

一、 申請廠商基本資料及健康食品查驗登記資料
Basic Information of the Applicant and Health Food Registration Information

二、 產品原料成分規格含量表
Specifications and Quantity of Ingredients

三、 產品之安全評估報告及其摘要表
Safety Assessment Report and the Summary Table

四、 產品之保健功效評估報告及其摘要表
Health Care Assessment Report and the Summary Table

五、 產品之保健功效成分鑑定報告及其檢驗方法、摘要表
Identification Report on Ingredients with Health Care Effect of a Product , its Inspection Method Employed and the Summary Table

六、 產品及其保健功效成分安定性試驗報告及其摘要表
Test Report on the Ingredient Stability of a Product, its Health Care Effect and the Summary Table

七、 產品製程概要
Summary of Manufacturing Process

八、 良好作業規範之證明資料及其摘要表
Documentary Evidence of Good Manufacturing Practices and the Summary Table

九、 產品衛生檢驗規格及其檢驗報告、摘要表
Sanitary Specifications, its Test Report and the Summary Table

十、 一般營養成分分析報告及其摘要表
General Nutrients Analysis Report and the Summary Table

十一、相關研究報告文獻資料及其一覽表
Relevant Research Reports and Literatures and the Overall List

十二、產品包裝標籤及說明書
Product package, Label and Information leaflet

十三、申請者公司登記或商業登記之證明文件影本
Copy of Registration Certificate of the Applicant's Corporation or Business

十四、完整樣品及審查費收據
Intact Sample and Review Fee Payment Receipt

十五、光碟片 2 份
Two discs

申請廠商 Applicant：　　（簽章 Seal）
負 責 人 Responsible Person：　　（簽章 Seal）
地　　址 Address：
聯 絡 人 Contact Person：
電　　話 Telephone No.：
電子郵件 Contact E-mail：
中　華　民　國　　年　　月　　日
Date: _____

一、申請廠商基本資料

Basic Information of the Applicant

申請廠商 Applicant	名稱 Name	
	營業所在地 Address of Business	
	負責人 Responsible Person	
	食品業者登錄字號 Food Business Registration No.	
	電話 Telephone No.	(　　)
	統一編號 Unified Business No.	
委託製造者 Contract Manufacturer	名　稱 Name	
	營業所在地 Address of Business	
	食品業者登錄字號 Food Business Registration No.	
	電話 Telephone No.	(　　)
製造工廠 Manufacturer	廠名 Factory Name	
	廠址 Factory Address	
	負責人 Responsible Person	
	食品業者登錄字號 Food Business Registration No.	
	電話 Telephone No.	(　　)
	工廠登記證編號 Factory Registration Certificate No.	
	統一編號 Unified Business No.	

一、健康食品查驗登記資料(一)

Health Food Registration Information (1)

<table>
<tr><td rowspan="2">品名
Product Name</td><td>中文品名
Chines Name</td><td></td></tr>
<tr><td>英文（原文）品名
English Name
(Source Language)</td><td></td></tr>
<tr><td colspan="2">原料成分含量
Ingredient Content</td><td></td></tr>
</table>

一、健康食品查驗登記資料(二)

Health Food Registration Information (2)

<table>
<tr><td rowspan="2">保健功效敘述及其原料成分
Description of Health Care Effect & Ingredients</td><td>保健功效敘述
Description of Health Care Effect</td><td>保健功效成分（原料）
Ingredients (Materials) with Health Care Effect</td></tr>
<tr><td>1.

2.</td><td>1.

2.</td></tr>
<tr><td rowspan="3">食用方法
Usage Instruction</td><td>攝　取　量
Amount of Intake</td><td></td></tr>
<tr><td>注 意 事 項
Precautions</td><td></td></tr>
<tr><td>警　　語
Warnings</td><td></td></tr>
</table>

一、健康食品查驗登記資料(三)

Health Food Registration Information (3)

<table>
<tr><td colspan="2">食品外觀形態
Appearance</td><td colspan="2"></td></tr>
<tr><td rowspan="7">包裝
Packaging</td><td rowspan="7">材　　質
Packaging Materials</td><td>1. 內包裝 Inner Packaging：</td><td>外包裝 Outer Packaging：</td></tr>
<tr><td>2. 內包裝 Inner Packaging：</td><td>外包裝 Outer Packaging：</td></tr>
<tr><td>3. 內包裝 Inner Packaging：</td><td>外包裝 Outer Packaging：</td></tr>
<tr><td>4. 內包裝 Inner Packaging：</td><td>外包裝 Outer Packaging：</td></tr>
<tr><td>5. 內包裝 Inner Packaging：</td><td>外包裝 Outer Packaging：</td></tr>
<tr><td>6. 內包裝 Inner Packaging：</td><td>外包裝 Outer Packaging：</td></tr>
<tr><td>7. 內包裝 Inner Packaging：</td><td>外包裝 Outer Packaging：</td></tr>
<tr><td rowspan="7"></td><td rowspan="7">重量（容量）
Weight (Volume)</td><td colspan="2">1.</td></tr>
<tr><td colspan="2">2.</td></tr>
<tr><td colspan="2">3.</td></tr>
<tr><td colspan="2">4.</td></tr>
<tr><td colspan="2">5.</td></tr>
<tr><td colspan="2">6.</td></tr>
<tr><td colspan="2">7.</td></tr>
<tr><td rowspan="3">保存方式
Preservation Method</td><td>保 存 方 法
Storage Method</td><td colspan="2"></td></tr>
<tr><td>保 存 條 件
Storage Conditions</td><td colspan="2"></td></tr>
<tr><td>保 存 期 間
Shelf life</td><td colspan="2"></td></tr>
</table>

一、健康食品查驗登記資料(四)

Health Food Registration Information (4)

申請查驗登記之緣由 **The reason(s) for filing the registration application**	

二、產品原料成分規格含量表

Specifications and Quantity of Ingredients

申請廠商 Applicant	
品 名 Product Name	

一、產品原料成分含量表 Quantity of Ingredients：

二、保健功效成分（原料）含量規格 Specifications of Ingredients (Materials) with Health Care effect：

三、產品之安全評估報告摘要表

Summary Table of Safety Assessment Report

申請廠商 **Applicant**	
品 名 **Name of Produc**	

一、原料確認(請擇一勾選)

Verification of Ingredients (Please check the appropriate one)

編號 Serial No.	內容物名稱 Name of Ingredients	傳統食材 Traditional Ingredients	符合「可供食品使用原料彙整一覽表」規定 Comply with the "List of Ingredients for Use in Food"	可同時提供食品使用之中藥材 Chinese herbal medicine concurrently usable for food	符合「食品添加物使用範圍及限量暨規格標準」規定 Comply with the "Standards for Specification, Scope, Application and Limitation of Food Additives"	非傳統食材或超出「可供食品使用原料彙整一覽表」規定 Non-traditional Food Ingredient or Going beyond the "List of Ingredients for Use in Food"	其他(請說明：例如有使用限制之中藥材) Others (Please specify; for example, use of restricted Chinese herbal medicine)
1							
2							
3							

二、安全性試驗 Safety Assessment

資料編號 **Serial No.**	實驗名稱 **Name of Experiment**	實驗對象 **Subject of Experiment**	實驗例數 **Number of Samples of Experiment**	攝取量・期間 **Amount of Intake & Duration**	實驗結果 **Result of Experiment**
3.1					
3.2					
3.3					

四、產品之保健功效評估報告摘要表

Summary Table of Health Care Effect Assessment Report

申請廠商 Applicant	
品 名 Product Name	

資料編號 Information Serial No	保健功效 Health Care Effect	實驗對象 Subject of Experiment	實驗例數 Number of Samples of Experiment	攝取量・期間 Amount of Intake & Duration	實驗結果 Result of Experiment
4.1					
4.2					
4.3					

五、產品之保健功效成分鑑定報告摘要表

Summary Table of Identification Report on Ingredients with Health Care Effect of a Product

申請廠商 Applicant	
品 名 Product Name	

第一批 1st（批號 Batch Number　　）：

第二批 2nd（批號 Batch Number　　）：

第三批 3rd（批號 Batch Number　　）：

六、 產品及其保健功效成分安定性試驗報告摘要表

Summary Table of Test Report on the Ingredient Stability of a Product and its Health Care Effect

申請廠商 Applicant			
品 名 Product Name			
資料編號 Serial Number	試驗項目 Testing Items	試驗對象 Subject of Testing	試驗摘要及結果 Summary and Result of Testing
第一批批號 No. of 1st Batch ： 6.1 6.2			
第二批批號 No. of 2nd Batch： 6.1 6.2			

七、產 品 製 程 概 要

Summary of Manufacturing Process

申請廠商 Applicant	
品 名 Product Name	

製造加工流程 Manufacturing Process：

八、良好作業規範之證明資料摘要表

Summary Table of Documentary Evidence of Good Manufacturing Practices

廠 名 Name of Factory	
品 名 Product Name	
合法工廠登記證號 Official Factory Registration Certificate No.	
其他品管系統認證資料清單 Checklist of Other Quality Management System Certification Information	
國外相關法規 （國產免填） Related Laws and Regulations of the Foreign Country (please ignore in case of domestically produced product)	
符合健康食品工廠良好作業規範相關資料清單 Checklist of Information Relating to the Compliance with the Good Manufacturing Practices for Health Food Manufacturer	製程管制文件 Manufacturing Process Control Document(s)： 1. 2. 3. 4. 品質管制文件 Quality Control Document(s)： 1. 2. 3. 4.

九、產品衛生檢驗規格及其檢驗報告摘要表

Summary Table of Sanitary Specifications and its Test Report

申請廠商 Applicant		
品　名 Product Name		
檢　驗　項　目 Items under Inspection	檢　驗　規　格 Inspection Specifications	檢　驗　結　果 Inspection Results
第一批批號 No. of 1st Batch： 1. 2. 3. 4. 第二批批號 No. of 2nd Batch： 第三批批號 No. of 3rd Batch：		

十、一般營養成分分析報告摘要表

Summary Table of General Nutrients Analysis Report

申請廠商 Applicant					
品 名 Product Name					
檢驗項目 Items under Inspection	檢驗結果 Inspection Results	檢驗項目 Items under Inspection	檢驗結果 Inspection Results	檢驗項目 Items under Inspection	檢驗結果 Inspection Results
第一批批號 No. of 1st Batch 產品每一份量 (公克/毫升) Amount per serving (g/ml)		第二批批號 No. of 2nd Batch 產品每一份量 (公克/毫升) Amount per serving (g/ml)		第三批批號 No. of 3rd Batch 產品每一份量 (公克/毫升) Amount per serving (g/ml)	
1. 熱量 Calorie 2. 蛋白質 Protein 3. 脂肪 Fats 飽和脂肪 Saturated Fats 反式脂肪 Trans Fats 4. 碳水化合物 Carbohydrates 糖 Sugar 5. 鈉 Sodium 6. 其他項目 Others		1. 熱量 Calorie 2. 蛋白質 Protein 3. 脂肪 Fats 飽和脂肪 Saturated Fats 反式脂肪 Trans Fats 4. 碳水化合物 Carbohydrates 糖 Sugar 5. 鈉 Sodium 6. 其他項目 Others		1. 熱量 Calorie 2. 蛋白質 Protein 3. 脂肪 Fats 飽和脂肪 Saturated Fats 反式脂肪 Trans Fats 4. 碳水化合物 Carbohydrates 糖 Sugar 5. 鈉 Sodium 6. 其他項目 Others	

十一、相關研究報告文獻資料一覽表

Oveall List of Relevant Research Reports and Literatures

申請廠商 Applicant				
品 名 Product Name				
編號 Serial No.	報告文獻資料名稱 Title of Reports or Literatures	作 者 Author	報告文獻資料出處 Source of Literatures	備 註 Remarks
11.1 11.2 11.3 11.4 11.5				

如為功效相關佐證文獻，請於備註欄填寫試驗模式，如人體、動物或離體試驗。

Where the literature information substantiates the Health Care Effect, please indicate the testing model in the field of "Remarks", for instance, human subject research, animal testing or in-vitro test.

十二、產品包裝標籤及說明書（一）

Product Package, Label and Information leaflet (1)

申請廠商 Applicant	
品 名 Product Name	
中 文 標 示 事 項 Labelling in Chinese	產 品 標 示 內 容 Product Label Content
1. 品名 Product Name	
2. 內容物及食品添加物名稱；其為二種以上混合物時，應依其含量多寡由高至低分別標示之，混合二種以上食品添加物，以功能性命名者，應分別標明添加物名稱 Name of Ingredients & Food Additive(s); those that contain two or more ingredients shall indicate the respective ingredients in descending order of proportion; in the case of a mixture of two or more food additives which are named according to its function shall indicate the name of each additive separately.	
3. 淨重、容量或數量 Net weight, volume, or quantity	
4. 有效日期、保存方法及條件 Expiration Date, Storage Method and Conditions	有效日期 Expiration Date： 保存方法 Storage Method： 保存條件 Storage Conditions：
5. 廠商名稱、地址。輸入者應註明國內負責廠商名稱、地址。 Name and address of the manufacturer. In case of an importer, please specify the name and address of the domestic manufacturer.	

十二、產品包裝標籤及說明書（二）

Product Package, Label and Information leaflet (2)

申請廠商 **Applicant**	
品 名 **Product Name**	

中 文 標 示 事 項 **Labelling in Chinese**	產 品 標 示 內 容 **Product Label Content**
6. 核准之功效 The Approved Health Care Effects	
7. 許可證字號（樣板）、「健康食品」字樣及標準圖樣（樣板） Reference number of the permit (sample), words of “Health Food” and standard logo (sample)	
8. 攝取量、食用時應注意事項、可能造成健康傷害以及其他必要之警語 Amount of Intake, precautions, possible health risks and other necessary warnings.	
9. 營養成分及含量（營養標示） Nutrient and its content (Nutrition facts)	
10. 保健功效成分及含量 Ingredients with Health Care Effect and its Content	

十二、產品包裝標籤及說明書（三）

Product Package, Label and Information leaflet (3)

申請廠商 Applicant	
品 名 Product Name	

十三、公司登記或商業登記之證明文件影本粘貼表

Table for Pasting of the Copy of Registration Certificate of the Applicant's Corporation or Business

申請廠商 Applicant	
品 名 Product Name	