健康食品查驗登記申請書表 (規格標準)-複審

APPLICATION FORM FOR REGISTRATION OF HEALTH FOOD

(Specification Standards)-Secondary 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.



填表須知

Instructions

一、一般注意事項 General Notifications

1. 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:產品包裝 標籤及說明書(一)、(二)、(三)。

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: Product Packaging Label and Instruction Manual (1), (2), (3).

2. 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.

3. 檢送之書件、資料、文獻,應以 A4 紙張 (210mm×297mm) 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,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.

 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).

5. 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.

二、填表說明 Instructions for Completing the Form

1. 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。

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.

健康食品查驗登記資料

Health Food Registration Information:

- (1) 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.
- (2) 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;食品添加物應使用衛生福利部公告「食品添加物使用範圍及限量暨規格標準」規定之品名。
 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; the names of the food additives shall be in compliance with the "Standards for Specification, Scope, Application and Limitation of Food Additives" as announced by the Mistry of Health and Welfare.
- (3) 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 health care effect shall be provided and after which, the "content (ingredient) with health health care effect" shall be specified in order of degree of efficacy of the health health care effect t. If more than one type of health health care effect is being applied, each type of health health care effect shall be listed.
- (4) 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 health care effect descriptions shall match those of the assessment and testing reports.

- (5) 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
- (6) 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.

(7) 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。

The field of "application reason(s)" shall clearly state the reason(s) why the product has health benefits.

2. 產品原料成分規格含量表

Specifications of the Raw Materials and Quantity of Ingredients of the Product:

- (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。原料之名稱應使用一般通用名稱,不得使用商品名;食品添加物應使用衛生福利部公告「食品添加物使用範圍及限量暨規格標準」規定之品名。

 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; the names of the food additives shall be in compliance with the "Standards for Specification, Scope, Application and Limitation of Food Additives" as announced by the Mistry of Health and Welfare.
- (2) 將製造廠出具之產品原料及成分規格書內容,摘錄於本表,並將正本檢附於附件處。
 The specifications of the raw materials and quantity of ingredients of the product issued by the manufacturer shall be summarized and included in the form and the original document shall be annexed as attachment.

3.產品之成分規格檢驗報告摘要表

Summary Table of Ingredients Specification Test Report of a Product:

(1) 成分規格檢驗報告應由製造廠或<u>委託其他檢驗機構</u>於一年內簽發者,摘錄於本表,並將原始報告 檢附於附件處並應將檢驗方法(包括:定性、定量)列示或檢附於報告中。

The ingredient specifications test report shall be issued by the manufacturer or an inspection body within one year. The report shall be summarized and included in the form and the original one shall be annexed as attachment. Moreover, the examination method, including qualitative analysis and quantitative analysis, shall be provided or attached to the report.

(2) 應檢附三批。

Three batches shall be attached.

4.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:

(1) 將<mark>製造廠</mark>或<mark>委託其他檢驗機構</mark>提具之安定性試驗報告(包括試驗方法、數據、結果)內容,摘錄 於本表,並將原始報告檢附於附件處。

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

(2) 應檢附三批。

Three batches shall be attached.

5.產品製程概要

Summary of Manufacturing Process:

- (1) 將製造廠提具之製造加工流程證明資料,摘錄於本表,並將原始證明檢附於附件處,並編訂頁碼。 The documents substantiating the manufacturing and processing process issued by the manufacturer shall be summarized and included in the form, and the original report shall be annexed as attachment and numbered.
- (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,應說明萃取方法及其溶劑;經濃縮者應說明濃縮之倍數。

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

6.良好作業規範之證明資料摘要表

Summary Table of Documentary Evidence Good Manufacturing Practices:

(1) 申辦「國產」健康食品查驗登記者,應將製造廠依「健康食品工廠良好作業規範」規定製作之相 關製程管制資料,摘錄於本表,並將原始相關文件資料檢附於附件處。

An applicant applying for "domestically produced" health food registration shall include in the form the summary of the relevant manufacturing process control information prepared by the manufacturer in accordance with the requirements of "Good Manufacturing Practices of Health Food Manufacturer" and annex the original documents and information as attachment.

(2) 申辦「輸入」健康食品查驗登記者,應將原製造廠提具之良好作業規範之官方證明文件內容,摘錄於本表,並將原始證明文件、原產國良好作業規範之法規全文、品管計畫書檢附於附件處。

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

7.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) 將製造廠提具之檢驗報告內容,摘錄於本表,並將原始報告檢附於附件處。如係委託其他檢驗機 構代驗者,比照辦理。

The test report provided by the manufacturer shall be summarized and included in the form and the original report shall be annexed as attachment. The foregoing requirement shall apply if the test is conducted by another inspection body.

(2) 應檢附三批。

Three batches shall be attached.

8.一般營養成分分析報告摘要表

Summary Table of General Nutrients Analysis Report:

(1) 將製造廠提具之檢驗報告內容,摘錄於本表,並將原始報告檢附於附件處。如係委託其他檢驗機 構代驗者,比照辦理。

The analysis report provided by the manufacturer shall be summarized and included in the form and the original report shall be annexed as attachment. The foregoing requirement shall apply if the analysis is conducted by another inspection body.

(2) 應檢附三批。

Three batches shall be attached.

9.產品包裝標籤及說明書(一)、(二)、(三)

Package, Label and Product Instruction Sheet (1), (2), (3):

- (1) 依健康食品管理法第十三條規定,將中 2) the content of the Chinese labels according to Article 13 of the Health Food C 文標示內容填入(一)、(二)。 Fill in (1) and (ontrol Act.
- (2) 將包裝、標籤、說明書點貼於(三)。標籤、說明書以點貼全型實物為原則,包裝等如因實物過大 或因包材之因素致不便於點時,得以實物之彩色照片代替點貼報核。

Paste the package, label, instruction sheet onto (3). In principle, the label and instruction sheet 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 packaging may be pasted onto the table as an

alternative.

10.公司登記或商業登記之證明文件影本點貼表

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

公司證明文件影本請縮印粘貼於本表。

Paste the copy of business registration certificate or document in reduced format onto the form.

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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) 2. 製造廠出具之產品原料及成分規格含量表正本 Original Copy of Specifications of the Raw Materials and Quantity of Ingredients) 3. 成分規格檢驗報告正本 Original Copy of the Ingredients Specification Test Report of a Product • • • • • (4. 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 5. 製造廠出具之產品製程概要資料正本 6. 良好作業規範之證明資料正本 Original Copy of Documentary Evidence of Good Manufacturing Practices • • • (7. 產品衛生檢驗規格及其檢驗報告正本 Original Copy of Sanitary Specifications and Analysis Report • • • • • • (8. 一般營養成分分析報告正本 Original Copy of General Nutrients Analysis Report • • • • • • • • • (

製造(輸入)健康食品查驗登記規格標準複審申請書

Application Form of Secondary Specification Standards for Registration of Produced (Imported) Health Food

			5生福 れ Ministry	利部 of Health and	d Welfare		
主	旨	: A	C公司排 日請查馬	疑□製造□ 檢登記。	輸入「中文品名:	1 ر	食品乙種,
		:T1	ne comp	any intends t	to □produce □import	(Foo	od Name),
說		:核	负附之言	書件、資料			
De:	script 子件、	ion: ˈ · 資	The atta 料逕送	ched docume 健康食品	ents and information include: 查驗登記委託審查單位)		
(Pl€	ease d	irectl	y sent th	e documents	and information to the appoint	ed body for the outs	sourced health
100	a proc	luct r	申請屬	on procedure.) 設商基本資	料及健康食品查驗登記	資料	
	Ξ		Basic Ir 產品原	nformation of 系料成分規	the Applicant and Health Foo 格含量表	od Registration Info	
	Ξ		Specific 產品之	cations of the こ成分規格	Raw Materials and Quantity 檢驗報告及其摘要表	of Ingredients of th	e Product
		1 `	Ingredi	ents Specifica	ation Test Report of a Product 效成分安定性試驗報告。	and the Summary 及其摘要表	Table
			Test Re	port on the In ary Table	ngredient Stability of a Produ	ct, its Health Care l	Effect and the
	五	<u>.</u> •	產品集	製程概要			
	六	,	艮好化	乍業規範之	acturing Process 證明資料及其摘要表		
	t	: `	Docum 產品債	entary Evide 訂生檢驗規	nce of Good Manufacturing P 格及其檢驗報告、摘要	'ractices and the Su 表	mmary Table
			Sanitar	y Specificatio	ons, its Test Report and the Sur 析報告及其摘要表		
			Genera	1 Nutrients A	analysis Report and the Summ	ary Table	
			Packag	D裝標籤及 e, Label and l	Product Instruction Sheet	•	
	+	- `	申請者 Copy o	子公司登記 f Certificate o	或商業登記之證明文件 of the Applicant's Corporation	影本 i or Business Regist	ration
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申	請腐	百	Applic	ant:		(簽章 Se	al)
負	責	人	Respon	nsible Persoi	n :	(簽章 Se	eal)
地	l.	址	Addre	ss •			
聯	絡	人	Contac	ct Person:			
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Ď	ate:	•	• •	- *	,	- V	

一、申請廠商基本資料

Basic Information of the Applicant

	名稱 Name		
	營業所在地 Address of Business		
申請	負責人 Responsible Person		
申請 廠商 Applicant	食品業者登錄字號 Food Business Registration No.		
	電話 Telephone No.	()
	統一編號 Unified Business No.		
	名 稱 Name		
委託製	營業所在地 Address of Business		
Contract Manufacturer	食品業者登錄字號 Food Business Registration No.		
	電話 Telephone No.	()
	廠名 Factory Name		
	廠址 Factory Address		
allo 1	負責人 Responsible Person 食品業者登錄字號		
製造工廠	Food Business Registration No.		
Manufacturer	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

Health Food Registration Information

品名 Name of Product	中文品名 Chines Name 英文 (原文) 品名 English Name (Source Language)				
食品	品外觀形態				
(顏色	、外觀、劑型)				
	rance of Food				
(color, ap	opearance, form)				
		1.	內包裝 Inner	' - '	Outer
		_	Packaging:	Packag	, ,
		2.	內包裝 Inner		Outer
	l L sér		Packaging:	Packag	, ,
	材質	3.	內包裝 Inner	' - '	Outer
	Materials	_	Packaging:	Packas	
包裝		4.	內包裝 Inner	1 '	Outer
Packaging		5.	Packaging: 內包裝 Inner	Packag	Guter
		υ.	Packaging:	Packas	
		1.	1 ackaging .	1 acras	51118
	里里(谷里) Weight (Volume)	2.			
		3.			
	(voidine)	4.			
		5.			
	保存方法				
保存方式	Storage Method				
Preservation	保存條件				
Method	Storage Conditions				
	保存期間				
	Shelf life				
	攝 取 量				
食用方法	Amount of Intake				
後用力法 Usage	注意事項				
Instruction	Precautions				
Inotiuction	警 語				
	Warnings				

二、產品原料成分規格含量表

Specifications of the Raw Materials and Quantity of Ingredients of the Product

申請廠商	
Applicant	
品名	
Product Name	
原料成分含量 Quantity of Ingredients	
成分規格含量 Specifications of Ingredients	

三、產品之成分規格檢驗報告摘要表

Summary Table of Ingredients Specification Test Report 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):

四、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	ī		
Applicant			
品名			
Product Nam	ie		
資料編號	試驗項目	試驗對象	試驗摘要及結果
Serial Number	Testing Items	Subject of	Summary and Result
		Testing	of Testing
第一批批號			
No. of 1st			
Batch:			
Adv. 33			
第二批批號			
No. of 2nd			
Batch:			
第三批批號:			
No. of 3rd			
Batch:			

五、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:

六、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)	
	製程管制文件
	Manufacturing Process Control Document(s):
	1.
符合健康食品工	
廠良好作業規範	2.
相關資料清單	3.
	4.
Information	
Relating to the	
Compliance with	٠. ١٠ ١٨ مد مد
the Good	品質管制文件
Manufacturing	Quality Control Document(s):
Practices for Health	1
Food Manufacturer	
	2.
	3.
	4.

七、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		T		1		
檢驗項	目		規		檢驗	結 果
Items under Ins	pection	Inspection	Specificat	tions	Inspecti	on Results
第一批批號:						
No. of 1st Batch:						
1.						
2.						
1. 2. 3. 4.						
4.						
第一批批號 :						
	•					
No. of 2nd Batch	•					
第三批批號:						
1 (or of or a Butch						
第二批批號: No. of 2nd Batch 第三批批號: No. of 3rd Batch:						

八、一般營養成分分析報告摘要表

Summary Table of General Nutrients Analysis Report

	申請廠商			General Nutr		<u>, </u>	<u> </u>	
	Applicant							
	品名							
	Product Name							
	檢驗項目	檢驗結		檢驗項目	檢驗結		檢驗項目	檢驗結
	Items under	果		Items under	果		Items under	果
	Inspection	Inspection		Inspection	Inspection	Inspection		Inspection
		Results			Results			Results
第	一批批號		第.	二批批號		第	三批批號	
No	o. of 1st Batch		No	. of 2nd Batch		No	o. of 3rd Batch	
1	品每一份量 \克/毫升)			品每一份量 \克/毫升)			品每一份量 △克/毫升)	
1.	熱量		1.	熱量		1.	熱量	
	Calorie			Calorie			Calorie	
2.	蛋白質		2.	蛋白質		2.	蛋白質	
	Protein			Protein			Protein	
3.	脂肪		3.	脂肪		3.	脂肪	
	Fats			Fats			Fats	
	飽和脂肪			飽和脂肪			飽和脂肪	
	Saturated Fats			Saturated Fats			Saturated Fats	
	反式脂肪			反式脂肪			反式脂肪	
	Trans Fats			Trans Fats			Trans Fats	
4.	碳水化合物		4.	碳水化合物		4.	碳水化合物	
	Carbohydrates			Carbohydrates			Carbohydrates	
	糖			糖			糖	
	Sugar			Sugar			Sugar	
5.	鈉		5.	鈉		5.	鈉	
	Sodium			Sodium			Sodium	
6.	其他項目		6.	其他項目		6.	其他項目	
	Others			Others			Others	
<u></u>			<u> </u>		<u>l</u>			

九、產品包裝標籤及說明書(一)

Package, Label and Product Instruction Sheet (1)

	申請廠商		, Luc		Prod	<u> </u>				(-)		
	•	·										
	Applican	.t										
_	品名											
-	roduct Na											
1	中文	標	示	事	項		產	品	標	示	內	容
	Labe	lling i	in Chi	nese				Produ	uct La	bel Co	ntent	
1.	品名											
	Product N	lame										
2.	內容物及	食品添	か物グ	名稱;	其為二							
	種以上混	合物時	手,應位	(其含	量多寡							
	由高至低	分別標	京示之 :	混合	二種以							
	上食品添	加物,	以功能	能性命	名者,							
	應分別標	明添加	口物名和	爯								
	Name of I	ngredi	ents &	Food								
	Additive(s	s); thos	se that	contair	n two							
	or more in	0			cate							
	the respec											
	descendin	0	-	-								
	the case of food addit											
	according											
	indicate th											
	separately											
3.	淨重、容	量或數	量									
	Net weigh	ıt, volu	ıme, or	quant	ity							
4.	有效日期	、保存	方法	及條件		有效し	ヨ期 E	xpirati	on Dat	e :		
	Expiration						•	1				
	and Condi			,		保存に	方法 S	torage	Metho	d:		
								O				
						保存值	条件 S	torage	Condit	tions:		
5. <i>i</i>	 廠商名稱、	地址	· 輸入	者應言	主明國							
	內負責廠商	有名稱	、地址	. •								
	Name and a		s of the	9								
	manufactur		ortor s	loace c	nocify							
	In case of ar the name ar	-	_									
	manufactur											

九、產品包裝標籤及說明書(二)

Package, Label and Product Instruction Sheet (2)

E	申請	廠商	5																
	App	licant	-																
	品	名																	
Pr	odu	ct Nar						ſ											
,	中	文	• •			事	項		產	•			標			•		容	
_		Labe			Chi	nese					Prod	uct	La	bel	Co	nten	t		
6.	,																		
r	The Approved Health Care Effects																		
7.		「證字 長及標					隶食品												
	Refe	erence	nur	nbei	of th	ne per	mit												
	(san	nple), v	wor	ds o	f "He	ealth F	Good"												
	and	standa	ard	logo	(san	nple)													
8.		マ昌、ノ	企 田		在注:	音重項	i 、 可 台	<u>E</u>											
0.	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				5														
	Am	ount o	f In	take	, prec	autio	ns,												
		sible h			-														
	nece	essary	wai	rning	gs.														
9.	營養	泰成分	及台	量	(營	養標元	≒)												
		rient a	nd	its co	onten	ıt (Nu	trition												
	fact	s)																	
10.		健功效	-																
	·				Healt	h Care	e Effect												
	and	its Co	nte	nt															
<u> </u>																			

九、產品包裝標籤及說明書(三)

Package, Label and Product Instruction Sheet (3)

申請廠商	
Applicant	
Applicant 品名	
Product Name	

十、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 Certificate of the Applicant's Corporation or Business

申請廠商	
申請廠商 Applicant	
品名	
Product Name	