Quotation and Engagement Letter

Whole then Customer +Sevice =Cananda FDA RA Services

Company: Customer Contact >>Compnay Title *
GUI/BAN: Customer Contact >>GUI / BAN
Contact Person: Customer Contact >>ContactPerson*
Phone: Customer Contact >>CompanyPhone
Mobile: Customer Contact >>MobilePhone
Email: Customer Contact >>Email*
Website: Customer Contact >>WebSite
Address: Customer Contact >>Address

** Process
Header>> Introduction

Dear Sir/Madam,

We are pleased to provide you the quotation of the below services in Taiwan with abbreviated symbols:
PRA-F-PMA Pre-market Review
--Step 1. NPN+Label
PRA-F-PLA-1 Product Licence application Class 1
PRA-F-PLA-2 Product Licence Application Class 2
PRA-F-PLA-3 Product Licence Application Class 3
PRA-F-LCR-3 Label Compliance Review
--step 2. Site Licensing +Testing/COA Assessment
PRA-F-SL :Site Licensing SL# application
PRA-F-Spec :Product Specification
--Step 3. Post-licence Compliance
PRA-F-COA :Certificate of Analysis
PRA-F-SCM :Annual Site Compliance Maintenance

Your product list are as below
health supplement products.

Plaese notice We assume your products will be categorized as Class 1, if not class 1, parameters will be changed as well.
And We also assume you will adopt your Canada Subsidiary or affiliated entity to apply Product Licence in Canada.
Besides, you will assign your own QAP (Quality Assurance Person) to be contact window with Canada relevant government entities.

Please review below parameters table, the assumption of your service items requirements, fee formula in each service item and calculation results.
For the detailed information, Please see the below appendix PRA.
The total service fee is as Summary Σ page no.3.

If unclear or a counter-proposal, please let us know.
If OK, please print the last page, sign it back, and we will immediately provide our services.

**Rights and obligations of both parties

1. Your Company's Rights and Obligations
Your Company shall provide Evershine with the information necessary for the Health Canada —Natural and Non-prescription Health Products Directorate (NNHPD) in accordance with existing laws, regulations and regulations.
The information provided by your company must be true and accurate.
If it does not conform to the facts, you will be responsible for the loss.
This agreement shall be deemed to be a power of attorney issued by your company to Evershine□
In the process of handling the change, change the basic data of Food Product , if the change should be negotiated with Evershine to solve, and pay for the repeated work caused to Evershine.

Your company can understand the process from Evershine at any time; Your company shall pay Evershine's expenses in time according to the agreement.
Your company should actively cooperate with Evershine in the process of entrustment and agency and should not interfere in the normal process.

2. Evershine's rights and obligations
Evershine should timely and accurately complete the entrusted agency business according to your request.
We shall not change the terms without authorization.
If there is any contradiction with the policy, we shall notify your company in time.
If Evershine accepts the authorization, if it is rejected because of the change of materials or policy adjustment, it needs to make up or amend in time, and the time limit for obtaining the NNHPD Food Product license shall be postponed.
To protect the legitimate rights and interests of your company and protect the integrity of your agency materials, Evershine will protect the known trade secrets.
Evershine has the right to terminate the agency business for the false change materials provided by your company and deduct the advance payment paid by you without refund.

3. Liability for breach of contract
Once the agreement is signed according to law, both parties shall conscientiously fulfill their respective rights and obligations and shall not modify or terminate the agreement without authorization.
If the agreement is terminated because of your company, the amount paid by your company cannot be recovered.
If you terminate the agreement because of Evershine, your prepaid service fee will be refunded to your company.
During the performance of the agreement, due to government laws, regulations, and policies, the principal-agent agreement cannot continue to be performed is automatically terminated.
After the termination of the contract, the unfulfilled part will no longer be performed, and the payment method of compensation for technical consulting shall be negotiated between the two parties.

4. Agreement Validity
From the date of signing of this Agreement until its contents described in this document are completed.

Contact windows:
Pharmacist Ariel Chuang
E-mail: Arielchuang@evershinecpa.com
or
Director Jerry Chu
E-mail: JerryChu@evershinecpa.com
+886-939-357-000

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Signature: _____

The following officer agrees on the content in this engagement letter.

Company Name: _____

Representative: _____

Signature: _____

Date: _____

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ItemCode	Definition	Formula	Required	Once	Once a Year
PRA-F-PMA	Pre-Market Review	=USD [200.00*2 FDA-FPRN_Food Products Review Number]	Yes, now	400.0	
PRA-F-PLA-1	Product Licence application Class 1	=USD [2,000.00*2 FDA-FPN_Food Product Numbers]	Yes, now	4,000.0	
PRA-F-PLA-2	Product Licence Application Class 2	=USD [2,400.00*2 FDA-FPN_Food Product Numbers]	Optional	0.0	
PRA-F-PLA-3	Product Licence Application Class 3	=USD [4,000.00*2 FDA-FPN_Food Product Numbers]	Optional	0.0	
PRA-F-LCR	Label Compliance Review	=USD [1,600.00*2 FDA-FPN_Food Product Numbers]	Yes, now	3,200.0	
PRA-F-SL	Site Licensing SL# application	=USD [4,100.00*1 S4g_Physical Site Numbers]	Yes, now	4,100.0	
PRA-F-Spec	Product Specification	=USD [1,500.00*2 FDA-FPN_Food Product Numbers]	Yes, now	3,000.0	
PRA-F-COA	Certificate of Analysis	=USD [1,300.00*6 FDA-batch_Batch]	Yes, now		7,800.0
PRA-F-SCM	Annual Site Compliance Maintenance	=USD [3,900.00*1 S4g_Physical Site Numbers]	Yes, now		3,900.0
PRA-F-GF	Government FEE	=USD 0.0	Yes, now	0.0	
Summary	Σ Estimated budget will be	=USD	Σ	14,700	11,700
		【Billing】	【(Native)】		
	Subtotal	Ex. Rate: 1	26,400.00	14,700.00	11,700.00
		【Parameters】			
FDA-batch:	Batch	6	Yes, now		
FDA-FPN:	Food Product Numbers	2	Yes, now		
FDA-FPRN:	Food Products Review Number	2	Yes, now		
S4g:	Physical Site Numbers	1	Yes, now		

Appendix # PRA Product Regulatory Affairs Application Services

▼PRA-F-PMA Pre-Market Review

[Once][Required]
=USD [200.00*2 FDA-FPRN_Food Products Review Number]
** Process
JobAndCharge>>ItemEdit

*We assume products will be two. If over or less, fee will depend on real product numbers.
*We will review the documents and let you know if the product is eligible to obtain the license.
*In order to assess the formula and provide a further quote on class 1 or Class 2 or class 3, we will require the following information:
・The official brand name of the product;
・ Dosage directions and dosage form;
・ The formula with the amounts of each medicinal ingredient and the non-medicinal ingredients. Please include the source materials (ie. leaf, root) for your medicinal ingredients.
・ For extracts, please ensure that they have a ratio (e.g. 4:1), and for standardized extracts, please ensure they have constituents and potencies.

▼PRA-F-PLA-1 Product Licence application Class 1

[Once][Required]
=USD [2,000.00*2 FDA-FPN_Food Product Numbers]
** Process
JobAndCharge>>ItemEdit

*We assume products will be two. If over or less, fee will depend on real product numbers.
*Only After Passing PRA-F-PMA Pre-Market Review, and being judged as Class I,this process will go ahead.

Class I
*產品完全符合已存在的官方 Monograph（成分、劑量、來源、用途、聲稱均一致）
*所有成分都在 NHPID 中且劑量與功效聲稱都相符
*約 60 天
Class I
Product fully attested to existing NHP monographs in the Natural Health Products Ingredients Database (NHPID) with no deviations (ingredients, dose, source, route, claims).

▼PRA-F-PLA-2 Product Licence Application Class 2

[Once][Optional] Optional means no need this service now, might become 'Required' in the future.
=USD [2,400.00*2 FDA-FPN_Food Product Numbers]
** Process
JobAndCharge>>ItemEdit

*We assume products will be two. If over or less, fee will depend on real product numbers.
*Only After Passing PRA-F-PMA Pre-Market Review, and being judged as Class II,this process will go ahead.

Class II
*產品部分符合 monograph，有輕微偏差（如劑量略不同、成分組合不同或聲稱語句略有不同），需附簡要文獻支持
*多成分配方、不同劑型（果凍、粉末）或輕微修改的聲稱
*約 90 天
Class II
Product partially attested to monographs or has minor deviations (e.g. claim wording, combination of ingredients). Requires summary evidence or scientific literature support.

▼PRA-F-PLA-3 Product Licence Application Class 3

[Once][Optional] Optional means no need this service now, might become 'Required' in the future.

=USD [4,000.00*2 FDA-FPN_Food Product Numbers]

** Process
JobAndCharge>>ItemEdit

*We assume products will be two. If over or less, fee will depend on real product numbers.
*Only After Passing PRA-F-PMA Pre-Market Review, this process will go ahead.

Class III
*產品不符合既有 monograph（新成分、新來源、新用途、新聲稱），需提交完整安全與功效資料
*新原料、新提取方式、新功效（如美白、抗糖化）
*約 210 天
Class III
Product not fully supported by monographs, new ingredients, new delivery forms, or new claims. Requires full scientific evidence package.

▼PRA-F-LCR Label Compliance Review

[Once][Required]
=USD [1,600.00*2 FDA-FPN_Food Product Numbers]

** Process
JobAndCharge>>ItemEdit

*We assume products will be two. If over or less, fee will depend on real product numbers.
*After getting Natural Product Number (NPN) through Product Licence Application (PLA), next step is Label Compliance Review.
*確認標籤內容、格式、語言、警語、字體大小、法定資訊皆符合法規。
*僅限標籤經合規確認後才能開始進口、生產與銷售。

▼PRA-F-SL Site Licensing SL# application

[Once][Required]
=USD [4,100.00*1 S4g_Physical Site Numbers]

** Process
JobAndCharge>>ItemEdit

*We assume site will be one. If over, fee will depend on real site numbers.
*文件清單總覽（中英對照）
A1:公司登記證明(Certificate of Incorporation);內容重點為:加拿大註冊公司證書，含公司名稱、編號、註冊省份。
A2:公司章程與董事名單(Articles of Incorporation & List of Directors);內容重點為:確認公司法定負責人與營運權限。
A3:加拿大地址證明(Proof of Canadian Address);內容重點為:可為租約、帳單或商業登記地址。
A4:母子公司關係聲明信(Letter of Association);內容重點為:若由台灣母公司持股，附上控制聲明。
B1:品質手冊(Quality Manual);內容重點為:概述品質方針、責任分工、SOP 管理、風險控制架構。
B2:標準作業程序(Standard Operating Procedures (SOPs));內容重點為:含以下主題：
- 文件控制
- 供應商審查與認證
- 進口批次放行流程
- 投訴與召回處理
- CAPA 程序
- 儲存與運輸管理

B3:紀錄表格範本(Record Forms & Logs);內容重點為:批次檢查表、偏差報告、放行簽核表、訓練紀錄等。
B4:QAP 簡歷與證明文件(QAP Curriculum Vitae & Certificates);內容重點為:含教育背景、QA 經驗證明、訓練記錄。
B5:員工訓練紀錄(Training Records);內容重點為:QAP、倉管、文件管理人員等訓練紀錄。
C1:外國製造廠清單(List of Foreign Manufacturers (Appendix C));內容重點為:所有製造 / 包裝 / 標示廠商的名稱與地址。
C2:外國 GMP 證明文件(GMP Evidence for Foreign Sites (Appendix D));內容重點為:提供 ISO、TGA、FDA、EU GMP 證書（3 年內有效）。
C3:供應商評估報告(Supplier Qualification Report);內容重點為:顯示你已審核供應商的 GMP 合規狀況。
D1:Site Licence 申請表(FRM-0034 Site Licence Application Form);內容重點為:Health Canada 官方主表，列出 Importer 職能。
D2:附件 A — Site Information(Appendix A — Site Information);內容重點為:加拿大營運地址、儲存地點。

D3:附件 B — QAP 資料(Appendix B — QAP Information);內容重點為:詳列 QAP 姓名、職稱、資格、履歷。
D4:附件 C — 外國製造廠名單(Appendix C — List of Foreign Manufacturers);內容重點為:與 C1 重疊部分，但為官方格式。
D5:附件 D — GMP 證明(Appendix D — GMP Evidence);內容重點為:與 C2 對應。
E1:Cover Letter（說明信）(Cover Letter);內容重點為:概述申請範圍、產品類型、GMP 認可方式。
E2:費用繳納證明（若適用）(Fee Payment Form / Receipt);內容重點為:若費用制度生效，附付款證明。

▼PRA-F-Spec Product Specification

[Once][Required]
=USD [1,500.00*2 FDA-FPN_Food Product Numbers]
** Process
JobAndCharge>>ItemEdit

*We assume products will be two. If over or less, fee will depend on real product numbers.
*PSF 必須包含的內容（Health Canada 官方建議格式）
PSF01:產品名稱(Product Name);文件內容為:英文商品名 + 通用名稱 (e.g. Hydrolyzed Collagen Drink)
PSF02:劑型(Dosage Form);文件內容為:Liquid / Capsule / Jelly Stick 等
PSF03:包裝形式(Packaging Type);文件內容為:例如：50 ml × 10 bottles / 15 g × 20 sticks
PSF04:成分表（藥用成分）(Medicinal Ingredients);文件內容為:每一成分名稱、來源、劑量、單位；符合 NHPID。
PSF05:成分表（非藥用成分）(Non-medicinal Ingredients);文件內容為:賦形劑、香料、甜味劑、防腐劑等。
PSF06:外觀說明(Description);文件內容為:顏色、氣味、味道、物理性狀。
PSF07:鑑別試驗(Identity Tests);文件內容為:針對主成分（例如膠原蛋白）之鑑定方法：如 FTIR / Peptide Profile。
PSF08:含量測試(Assay / Potency);文件內容為:含量測試方法、標準、允收範圍（±10%）。
PSF09:純度 / 污染物測試(Purity Tests);文件內容為:重金屬（Pb, Cd, As, Hg）、微生物限度、殘留溶劑等。
PSF10:物理 / 化學測試(Physical / Chemical Tests);文件內容為:pH、比重、黏度、外觀穩定性等。
PSF11:保存條件(Storage Conditions);文件內容為:“Store below 25 °C, protect from light and moisture.”
PSF12:有效期(Shelf Life / Expiry);文件內容為:例：2 years from manufacture date；附穩定性依據。
PSF13:測試方法參考(Test Methods Reference);文件內容為:USP / AOAC / In-house validated method。
PSF14:批次放行標準(Acceptance Criteria Summary);文件內容為:每項測試項目之允收範圍與合格/不合格標準。
PSF15:簽核欄位(Approval Signatures);文件內容為:QA / QAP / Technical Manager 簽名與日期。

▼PRA-F-COA Certificate of Analysis

[Once a Year][Required]
=USD [1,300.00*6 FDA-batch_Batch]
** Process
JobAndCharge>>ItemEdit

*We assume you will execute 6 batches per year. If More than 6 batches, will charge USD1300 per batch.
*COA 文件格式要求 (Certificate of Analysis Format)
Header : Product name, batch/lot number, manufacture date, expiry date
Test parameters : Identity, purity, potency, microbial limits, heavy metals, etc.
Specifications : Accepted limits / criteria
Results : Measured values with pass/fail
Test method reference : e.g. USP, AOAC, in-house validated method
Analyst / QA signature : Name, position, signature, date
Laboratory information:Lab name, address, contact
QAP approval:Final sign-off before release

▼PRA-F-SCM Annual Site Compliance Maintenance

[Once a Year][Required]
=USD [3,900.00*1 S4g_Physical Site Numbers]
** Process
JobAndCharge>>ItemEdit

*We assume site will be one. If over, fee will depend on real site numbers.
*PSF 附屬支援文件（要放入產品檔案夾 Product File）
Health Canada 建議每個產品的「Product File」應包含以下文件（均與 PSF 關聯）：
文件名稱 目的 / 說明
1 Product Specification Sheet (PSF) 核心文件。
2 Master Formula Record (MFR) 描述配方組成、製程、填充、包裝步驟。
3 Product Licence (NPN Certificate) Health Canada 核准的產品許可證。
4 Stability Study Summary 穩定性研究摘要，用以支持有效期限。
5 Analytical Method Validation Summary 若使用內部方法，須提供驗證報告摘要。
6 Reference Standards List 用於分析的標準品清單與來源。
7 Lab Testing SOP / Method Sheet 每個測試項目的操作程序與儀器方法。
8 Sample COA (typical batch) 代表性批次的分析報告（COA）。
9 QAP Approval Record QAP 簽署文件，確認此 PSF 為現行版本。
10 Change Control Log 若配方或規格變更，紀錄版本號與修訂原因。

* 重點：
這一套文件整合起來即是 “Product Master File (PMF)” 或 “Product Dossier” 。
PSF 是其中的品質核心文件，Health Canada 稽查時必查。

▼PRA-F-GF Government FEE

[Once][Required]
=USD 0.0

** Process
JobAndCharge>>ItemEdit

*This fee will be paid to the relevant Canadian government authorities or designated entities.
*We will make the payment on your behalf and be reimbursed upon providing the official receipt issued by the Canadian government or its authorized entities.
*When the prepaid amount exceeds USD 500, we will request advance payment from you.

●Canada Food Regulatory Affairs Application Services

** Process
JobAndCharge >>ItemEdit>>PRA: Product Regulatory Affairs Application Services

Payment Terms:
*Above quotation . not include VAT
*After sign up engagement letter, pay fee of PRA-FOOD-PMA Food Pre-market review
*when you decide to start STEP 1. NPN + Label
Pay fee of PRA-F-PLA-1 or PRA-F-PLA-2 or PRA-F-PLA-3 +PRA-F-LCR。
*when you decide to start Step 2. Site Licensing +Testing/COA Assessment
Pay fee of PRA-F-SL and PRA-F-Spec
*when you decide to start Step 3.Post-licence Compliance
Pay fee of PRA-F-COA,PRA-F-SCM to us.

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Appendix # CNS

●Brief Procedures

Footer>>BriefProcedure ** Process

Any foreign 天然健康產品 want to import to Canada for selling , they need to follow steps:

STEP 1. NPN + Label
1.1: Do Pre-market Review to confirm if your products are eligible to getting Product Licence from Health Canada — Natural and Non-prescription Health Products Directorate (NNHPD).
請參考PRA-F-PMA Pre-Market Review。
1.2: If passing Pre-market Review, Set Up your own Canada Subsidiary.
1.3: Then assign QAP quality assurance person to be contact window with NNHPD.
1.4: Then do Product Licence Application (PLA) application to gain Natural Product Number (NPN).
請參考PRA-F-PLA-1 or PRA-F-PLA-2 or PRA-F-PLA-3。
1.5: After getting Natural Product Number (NPN) , then doing Label Compliance Review.
請參考PRA-F-LCR Label Compliance Review。

Step 2. Site Licensing +Testing/COA Assessment
2.1 確認公司在加拿大合法設立，並屬於「進口商（Importer）」類型
2.2 建立符合 NHP GMP 的品質制度、SOP、批次追蹤、文件保存系統
2.3 蒐集與撰寫所有 Site Licence 申請表、附表與證明，取得Site License Number（SL#)。
請參考PRA-F-SL Site L incensing SL# application。
2.4 使用 NHP Online System (ePLA) 線上向 Health Canada 遞交申請
2.5 Product level-Testing/COA (Testing & Certificate of Analysis)Assessment to Define specs for PLA (once per SKU),一次性,文件名稱為Product Specification Sheet (PSS)。
請參考PRA-F-Spec Product Specification。

Step 3. Post-licence Compliance
Ready-to-sell pre-requirements: NPN+ Compliant label+ Site License Number（SL#）
3.1 Batch level-COA (Certificate of Analysis) to Confirm each lot meets specs,每批次,文件名稱為Certificate of Analysis。
請參考PRA-F-COA Certificate of Analysis。
3.2 Site Level to Ensure system control & traceability,持續,文件名稱為SOPs + GMP + QAP Sign-off。
請參考PRA-F-SCM Annual Site Compliance Maintaneance 。

●Reference and Information

Footer>>CNS(reference and information) ** Process

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*Evershine are with 100% owned affiliates in below cities(202406):
Taipei, Beijing, Shanghai, Xiamen, Shenzhen, Singapore, the United States (San Francisco, New York, Houston, Phoenix), Japan (Tokyo), South Korea (Seoul), Vietnam (Hanoi), Philippines (Manila), Thailand (Bangkok), Malaysia (Kuala Lumpur), Indonesia (Jakarta), Australia (Melbourne), India (New Delhi), Germany (Frankfurt, Berlin), United Kingdom (London), Toronto (Canada), France (Paris), Netherlands (Amsterdam), Mexico (Mexico City),Italy (Milan).

*Evershine have also provided services to clients in the following cities:
China (Fuzhou, Putian, Quanzhou, Changzhou, Pingtan, Nanjing, Guangzhou, Dongguan, Suzhou, Kunshan, Tianjin, Qingdao), Vietnam (Ho Chi Minh), Italy (Rome), the United States (Miami, Atlanta, Detroit, Seattle) , Turkey (Istanbul), Germany (Munich and Hamburg), Spain (Barcelona), Czech Republic (Prague), Romania (Bucharest), Bangladesh (Dhaka), India (Mumbai, Bangalore, Chennai), Australia (Sydney), Japan (Osaka), Mexico (Tijuana, Monterrey).

*Potential serviceable cities (2 months preparation period):
For any other cities you want to expand, please refer to the following two websites, IAPA www.iapa.net and LEA https://www.leaglobal.com/ . Both are the member firms of the international accounting firms of Evershine.
There are about 900 member firms with 38,000 staff, in 450 cities. As long as you are in these cities, we can arrange services for you.
Please contact us by: headquarter@evershinecpa.com
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