

If you intend to import drugs for personal use, you have to apply for a pharmaceutical import permit in Taiwan.

You will need to finish the attachments and prepare the following items:

1. A copy of your passport
2. Customs claim paper
3. Doctor's prescription (prescription medicine)
4. Package Inserts for the drugs prescribed or needed for personal use .
5. Application form . ( 貨品進口同意書申請書; Application for import certificate)
6. Assurance Statement of Drug Application for Personal Use

Please send the above documents to the following address:

台北市南港區昆陽街 161-2 號

No 161-2, Kunyang St. Nangang District Taipei City 115-61

If there are no additional question, we will send the approval back in few days.

If you have further question, feel free to mail to Miss. Chen E-Mail :  
dginfo@fda.gov.tw

Tel : 02-27877691 (if not available, try the other number 02-2787-7478)

Division of Medicinal Products  
Food and Drug Administration  
Ministry of Health and Welfare. Taiwan

## Assurance Statement of Drug Application for Personal Use

I, \_\_\_\_\_, for the reason of personal use, intend to apply for the import of the following drug(s).

(Please indicate item information in details, eg.xxx 200 tab/bottle, 1 bottle)

This Statement, hereby, assures proper utilization of the product in concern.

### Note:

1. If the product is approved for personal use, it will be subject to regular auditing by the Department of Health and local health authorities.
2. Since the product imported is not licensed in Taiwan, drug relief regulation doesn't apply in case of adverse drug reaction. The applicant, as well as prescribing physicians, must be responsible for the safety of the product. Due precaution is advised before making the application.
3. The applicant should guarantee strict personal use of the product which is not intended for sale, transferal, or any other indications.

Signature of the applicant:

Identification number / passport number:

Telephone :

Contact address:

Date: (mm/dd/yy)

受理機關：衛生署福利部食品藥物管理署

適用貨品：中藥、西藥(藥品、原料藥)、醫療器材、化粧品、組織/器官

貨品進口同意書申請書

APPLICATION FOR IMPORT CERTIFICATE

第一聯：受理機關存查聯

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①申請人 Applicant		④生產國別 Country of origin	
③統一編號 Unified code (個人申請案，則請填寫身分證字號)		⑤起運口岸 Shipping port	
③地址及電話 Address and Tel. No.		⑥賣方國家 Country of seller	
⑦項次 Item	⑧貨名、規格、廠牌及製造廠名稱 Description of Commodities Spec. and Brand or Maker, etc.	⑩數量 Qty	⑪單位 Unit
備註 Remarks		同意書號碼 Certificate No.	
<p>■個人自用：(1)身分證影本(2)國際包裹招領單或海關提單影本(3)貨品外盒、說明書(仿單)或目錄(4)醫院出具之診斷證明書及處方(一般成藥、口服維生素製劑、化粧品除外)</p> <p><input type="checkbox"/>查驗登記：<input type="checkbox"/>藥品及醫療器材：(1)藥商許可執照影本(2)貨品外盒、說明書(仿單)或目錄(3)送驗通知單</p> <p><input type="checkbox"/>化粧品：(1)營利事業登記證影本(2)國際包裹招領單或海關提單影本(3)貨品外盒、說明書(仿單)或目錄</p> <p><input type="checkbox"/>臨床試驗用藥物(藥品/醫療器材)：衛生署同意函影本</p> <p><input type="checkbox"/>展示用醫療器材：(1)製造國別、廠名(2)器材名稱、型號、數量(3)展示行程、用途、理由(4)藥商許可執照影本(5)醫學會、學術機構或醫療院所同意函(6)產品之仿單(說明書或目錄)及譯本(7)發生游離輻射之器材須加附原能會同意函(8)切結書</p> <p><input type="checkbox"/>少量醫院專案進口：(1)簡要治療計劃書(2)人體試驗委員會同意書(3)病人同意書(4)原產國上市證明或其他證明器材已上市之資料(5)產品之仿單(說明書)或目錄(6)該產品無法以衛生署已核准上市產品所取代之說明</p> <p><input type="checkbox"/>自用原料藥：(1)藥品製造許可證影本 張(許可證字號 ) (2)原料之檢驗規格、方法、檢驗成績書(載明批號、檢驗日期及認定人員之簽名)</p> <p><input type="checkbox"/>進口器官組織(移植用)：請檢附安全證明文件</p> <p><input type="checkbox"/>進口器官組織(研究用)：請檢附安全證明文件</p> <p><input type="checkbox"/>政府機關進口防疫用疫苗</p>		核准日期 Issue Date 104/03/26	
		有效日期 Expiration Date	
		申請人蓋章 Signature of Applicant	
		收件號碼	收件日期

本案實到貨物之商品分類號列 (CCC Code)，由海關依權責認定

申請書續頁

⑦項次 Item	⑧貨名、規格、廠牌或廠名等 Description of Commodities Spec. and Brand or Maker, etc.	⑨	⑩數量 Q'ty	⑪單位 Unit
同意書號碼 Certificate No.		收件號碼		
		收件日期		

受理機關：衛生署福利部食品藥物管理署  
 適用貨品：中藥、西藥(藥品、原料藥)、醫療器材、化粧品、組織/器官

貨品進口同意書  
 IMPORT CERTIFICATE

第二聯：申請人報關用聯

共 頁 第 頁

①申請人 Applicant		④生產國別 Country of origin	
②統一編號 Unified code (passport Number)		⑤起運口岸 Shipping port	
③地址及電話 Address and Tel. No.		⑥賣方國家 Country of seller	
④項次 Item	⑧貨名、規格、廠牌及製造廠名稱 Description of Commodities Spec. and Brand or Maker, etc.	⑩數量 Qty	⑪單位 Unit
備註 Remarks <input checked="" type="checkbox"/> 產品療效與安全性自行負責 <input checked="" type="checkbox"/> 產品不得販售 <input type="checkbox"/> 產品不得用於臨床 <input checked="" type="checkbox"/> 產品以單包裝為限 <input type="checkbox"/> 准於部份進口 <input type="checkbox"/> 其他等可供核准時勾選用 <input checked="" type="checkbox"/> 本同意書限一次使用 <input type="checkbox"/> 本同意書限多次使用 <input type="checkbox"/> 進口後應於三個月內檢齊該原料完整之批次檢驗成績書送處備查，倘未於該期限內補齊者，即不准再行以後補成績書方式為之		同意書號碼 Certificate No.	
		核准日期 Issue Date	
		有效日期 Expiration Date	
①		核准機關簽章 Approving Agency Signature	
②			
③			
④			
⑤			
		收件號碼	
		收件日期	

本案實到貨物之商品分類號列 (CCC Code)，由海關依權責認定

同意書續頁

⑦項次 Item	⑧貨名、規格、廠牌或廠名等 Description of Commodities Spec. and Brand or Maker, etc.	⑨	⑩數量 Q'ty	⑪單位 Unit
同意書號碼 Certificate No.		收件號碼		
		收件日期		