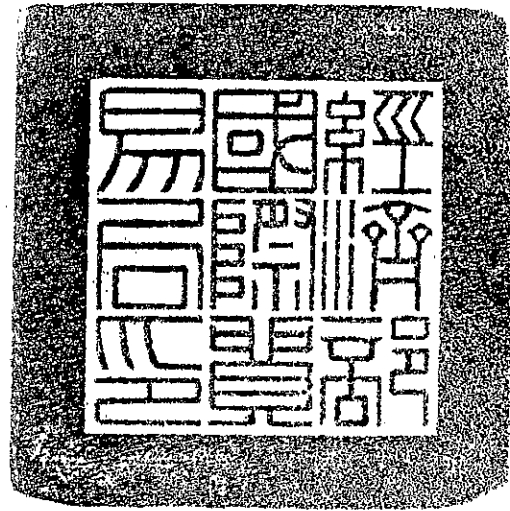


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經濟部國際貿易局 公告

發文日期：中華民國102年6月25日
發文字號：貿服字第1020151494號
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主旨：公告自本(102)年8月1日起CCC1905.90.10.00-3「盛裝藥物用之空囊」及CCC9602.00.41.00-5「藥用膠囊」2項貨品刪除輸入規定代號「802」，增列輸入規定代號「821」。

依據：貨品輸入管理辦法第8條及行政院衛生署食品藥物管理局本年3月27日FDA食字第1028002958號函。

公告事項：

- 一、為強化膠囊類產品輸入邊境管理之需要，自本年8月1日起CCC1905.90.10.00-3「盛裝藥物用之空囊」及CCC9602.00.41.00-5「藥用膠囊」2項貨品刪除輸入規定代號「802」，增列輸入規定代號「821」。
- 二、輸入規定代號「821」內容為：（一）進口人用藥品，應依503規定辦理（二）進口動物用藥品，應依406規定辦理（三）進口食品及其相關產品，應依F01辦理（四）進口非屬上述項目者，應註明「本貨品非屬人用藥品、動物用藥品、食品及其相關產品」字樣，免依上述規定辦理。
- 三、檢附貨品輸入規定變更明細表1份。

局長 張俊福

貨品輸入規定變更明細表

項次	貨品號列	貨名	原列輸入規定	改列輸入規定
1	1905.90.10.00-3	盛裝藥物用之空囊 Empty cachets of a kind suitable for pharmaceutical use	802	821
2	9602.00.41.00-5	藥用膠囊 Capsules for pharmaceutical products	802	821
號列項數：2				
輸入規定代號說明				
(空白)	准許（免除簽發許可證）。 Import permitted (free from licensing)			
406	進口動物用藥品（包括原料藥、製劑及生物藥品）：（一）應檢附(1)動物用藥品販賣業許可證影本及行政院農業委員會核發之輸入動物用藥品許可證影本（非輸入動物用藥品許可證之持有者，應加附原證持有者之授權文件或於該許可證影本上加蓋授權使用之章戳原本），或(2)含該成分製劑之製造動物用藥品許可證影本及行政院農業委員會動植物防疫檢疫局核發之「動物用藥品自用原料藥輸入審核通知書」。（二）如屬樣品、贈品，應檢附行政院農業委員會動植物防疫檢疫局核發之「動物用藥品樣品、贈品輸入審核通知書」。 For importation of veterinary medicines (including raw material pharmaceutical products, pharmaceutical products and biological products): (1) a) A photocopy of veterinary medicine import license issued by the Council of Agriculture, Executive Yuan (Non-licensed importers shall submit an application together with an authorization documentation issued by the owner of such a license or a photocopy of the medicine license with a stamp indicating that authorization to use the license has been granted) and a photocopy of a veterinary drug dealers license are required, or b) a "Notice For Importing Raw (Bulk) Material Limited to The Veterinary Drug Manufacturer Self Use" issued by the Bureau of Animal and Plant Health Inspection and Quarantine, Council of Agriculture, Executive Yuan, and a photocopy of a license for manufacturing veterinary drug containing the pharmaceutical products are required. (2) If the imported goods are samples or gifts, a "Notice for Importing Veterinary Medicines Samples" issued by the Bureau of Animal and Plant Health Inspection and Quarantine, Council of Agriculture, Executive Yuan is required.			
503	進口人用藥品（包括製劑、原料藥、助診藥類及人用生物製劑）：應檢附（一）藥商許可執照影本及行政院衛生署核發之（輸入）藥品許可證影本，或（二）行政院衛生署核發之同意文件。Importation of drugs (including pharmaceutical products, active pharmaceutical ingredients, diagnostics and biological products) for human use requires either of the following: (1) a photocopy of the drug (import) license issued by the Department of Health, Executive Yuan together with a photocopy of the license of the pharmaceutical firm; or (2) an approval issued by the Department of Health.			
802	（一）進口人用藥品，應依503規定辦理（二）進口動物用藥品，應依406規定辦理。 (1) Importation of medicines for human use is governed by the regulation of "503". (2) Importation of veterinary medicines is governed by the regulation of "406".			
821	（一）進口人用藥品，應依503規定辦理（二）進口動物用藥品，應依406規定辦理（三）進口食品及其相關產品，應依F01辦理（四）進口非屬上述項目者，應註明「本貨品非屬人用藥品、動物用藥品、食品及其相關產品」字樣，免依上述規定辦理。」。 (1) Importation of medicines for human use is governed by the regulation of "503". (2) Importation of veterinary medicines is governed by the regulation of "406". (3) Importation of foods and food-relevant products is governed by the regulation of "F01". (4) Importation of commodity not belong to the aforesaid items shall be exempted from "the said regulations, but a clear indication that the commodity is not to be used as human medicines, veterinary medicines, foods and food-relevant products" is required.			
F01	輸入商品應依照行政院衛生署發布「輸入食品及相關產品查驗辦法」規定，向行政院衛生署食品藥物管理局申請辦理輸入查驗。 Importation of foods shall follow the "Regulations for Inspection of imported Food and Food-relevant produces" promulgated by the Department of Health of the Executive Yuan. The importer shall apply for inspection to the Food and Drug Administration, Department of Health, Executive Yuan (FDA).			