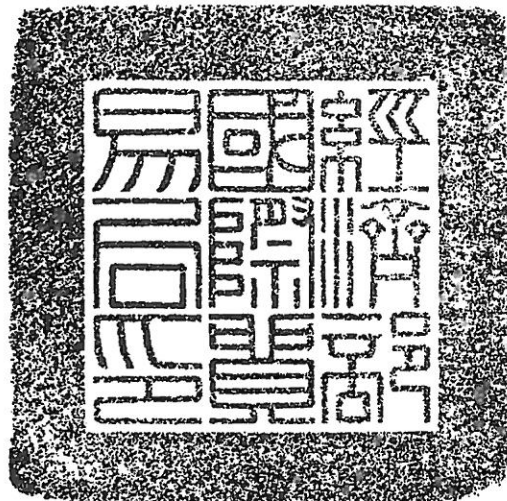


檔		保存年限
號	/ /	

經濟部國際貿易局 公告

發文日期：中華民國106年11月6日
發文字號：貿服字第1067030329號
附件：如文(1067030329-1.pdf)



主旨：公告自106年12月1日起CCC3001.90.90.00-5「其他未列名之已調製人類或動物物質，供醫療或預防疾病之用者」1項貨品號列之輸出規定代號修正為「807」，輸入規定代號修正為「836」，並列入「海關協助查核輸出貨品表」及「海關協助查核輸入貨品表」。

依據：貨品輸出管理辦法第8條第1項、貨品輸入管理辦法第8條第1項、衛生福利部106年7月5日衛授食字第1069903628號函及衛生福利部疾病管制署106年7月12日疾管感字第1060500384號函。

公告事項：檢附貨品輸出入規定變更明細表1份如附件。

局長 楊珍妮

經濟部國際貿易局
貨品輸出入規定變更明細表

貨品號列	貨名	原輸入規定	列改輸入規定	原輸出規定	列改輸出規定
3001.90.90.00-5	其他未列名之已調製人類或動物物質，供醫療或預防疾病之用者 Other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included	835 B01	836 B01	804	807

號列頁數: 1

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」。

經濟部國際貿易局
貨品輸出入規定變更明細表

貨品號列	貨名	原列規定	改列規定	原列規定	改列規定
------	----	------	------	------	------

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.

- 501 應檢附衛生福利部同意文件。
Approval from the Ministry of Health and Welfare is required.
- 506 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衛生福利部核發之（輸入）藥品許可證影本，或（二）衛生福利部核發之同意文件。（三）如屬專供研究或實驗用之抗生素及其衍生物，於進口報單填列專用代碼 DHM99999999506，免依上述規定辦理。

經濟部國際貿易局
貨品輸出入規定變更明細表

貨品號列	貨名	原輸入規定	改輸入規定	原輸出規定	改輸出規定
------	----	-------	-------	-------	-------

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 Ministry of Health and Welfare together with a photocopy of the license of the pharmaceutical firm; or (2) an approval issued by the Ministry of Health and Welfare.(3)Importing antibiotics and their other derivatives for research use, or experiment use should list the special code DHM9999999506 on the import application and is exempted from the above regulations.

835

(一) 進口人用藥品，應依506規定辦理 (二) 進口動物用藥品，應依406規定辦理。(三) 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」字樣，免依上述規定辦理。

(1) Importation of medicines for human use is governed by the regulation of "506".(2) Importation of veterinary medicines is governed by the regulation of "406".(3) Importation of commodity not belong the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as human use, veterinary medicines" is required.

836

(一) 進口人用藥品、人類檢體：1.應依506規定辦理。2.進口研究用、教學或檢驗用之「非感染性人類檢體」，於進口報單填列專用代碼DHM99999999990。

(二) 進口人類細胞株：1.應依501規定辦理。2.供研究用之人類細胞株（含人類幹細胞株、人類胚胎幹細胞株），於進口報單填列專用代碼 DHK99999999999。(三) 進口動物用藥品，應依406規定辦理。(四) 進口非屬上述項目者，應註明「本貨品非屬人用藥品、人類檢體、人類細胞株、動物用藥品」字樣，免依上述規定辦理。

經濟部國際貿易局
貨品輸出入規定變更明細表

貨品號列	貨 名	原 則	改 列	原 則	改 列	輸 入 規 定	輸 入 規 定	輸 出 規 定	輸 出 規 定
------	-----	-----	-----	-----	-----	---------	---------	---------	---------

1.Imported human drug products, human specimens:(1)Should follow Customs rule 506(2)The dedicated code (number) of Import declaration (application for import) for Imported Non-infectious human specimens for research, teaching or testing is DHM99999999990.2.Imported human cell lines:(1)Should follow Customs rule 501.(2)The dedicated code (number) of Import declaration (application for import) for Imported human cell lines (including human stem cell lines, human embryonic stem cell lines)for research is DHK99999999999.3.Importation of veterinary medicines is governed by the regulation of "406".4.Importation of commodity not belong the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as human medicines or veterinary medicines, and is not a human cell line or a specimen of human or animal origin" is required.

B01

進口時，應依行政院農業委員會動植物防疫檢疫局編訂之「應施檢疫動植物品目表」及有關檢疫規定辦理。

Importation shall be subject to the prescription set forth in the Table of Commodities Subject to Legal Animal & Plant Quarantine compiled by the Bureau of Animal and Plant Health Inspection and Quarantine Council of Agriculture, Executive Yuan.

輸出規定代號說明

(空白) 准許 (免除簽發許可證)。
Export permitted (free from licensing)

經濟部國際貿易局
貨品輸出入規定變更明細表

貨品號列	貨 名	原 則	改 定	原 則	改 定	列 出	列 出
		輸入規定	輸入規定	輸出規定	輸出規定	輸出規定	輸出規定
523	一、出口本項下人用藥品，應檢附衛生福利部核發之藥品許可證影本。（屬外貨復出口者，免附）二、出口非屬人用藥品，於出口報單填列專用代碼DHM9999999523，免依上述規定辦理。						
	(1)For exportation of commodities under this item of medicines for human use, a photocopy of medicine permit issued by the Ministry of Health and Welfare is required. (For re-export of the imports, the photocopy of the medicine permit is not required)(2)For exportation of medicines not for human use, should list the special code DHM9999999523 on the export application and is exempted from the above regulations.						
524	應檢附衛生福利部同意文件。（屬外貨復出口者，免附）						
	Approval from the Ministry of Health and Welfare is required.(For re-export of the imports, the approval is not required)						
525	出口本項下動物用藥品，應檢附行政院農業委員會核發之中華民國核准輸出動物用藥品證明書。（屬外貨復出口者，免附）						
	For exportation commodities under this item of medicines for animal use, a certificate for export of medicines for animal use issued by the Council of Agriculture, Executive Yuan, is required.(For re-export of the imports, the certificate is not required)						
804	（一）出口人用藥品，應依「523」規定辦理。（二）出口動物用藥品，應依「525」規定辦理。						
	(1) Exportation of medicines for human use is governed by the regulation of "523". (2) Exportation of veterinary medicines is governed by the regulation of "525".						

經濟部國際貿易局
貨品輸出入規定變更明細表

貨品號列	貨名	原輸入規定	改列輸入規定	原輸出規定	改列輸出規定
807	(一) 出口人用藥品、人類檢體：1.應依「523」規定辦理。2.出口研究用、教學或檢驗用之「非感染性人類檢體」，於出口報單填列專用代碼DHM9999999990。(二) 出口人類細胞株：1.應依「524」規定辦理。2.出口供研究用之人類細胞株(含人類幹細胞株、非屬本國人之人類胚胎幹細胞株)，於出口報單填列專用代碼DHK9999999999。(三) 出口動物用藥品，應依「525」規定辦理。(四) 出口非屬上述項目者，應註明「本貨品非屬人用藥品、人類檢體、人類細胞株、動物用藥品」字樣，免依上述規定辦理。				
	1.Exportation human drug products, human specimens:(1)Should follow Customs rule 523. (2)The dedicated code (number) of Import declaration (application for export) for Imported Non-infectious human specimens for research, teaching or testing is DHM99999999990.2.Exported human cell lines:(1)Should follow Customs rule 524.(2) The dedicated code (number) of Export declaration (application for import) for Imported human cell lines (including human stem cell lines, human embryonic stem cell lines)for research is DHK99999999999.3.Exportation of veterinary medicines is governed by the regulation of "525" 4.Importation of commodity not belong the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as human medicines or veterinary medicines, and is not a human cell line or a specimen of human or animal origin" is required.				