

經濟部國際貿易局
貨品輸入規定變更明細表

報表代號：FHBE010R01
程式代號：FHBE010
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列印日期：105/07/27
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貨品號列	貨名	原列輸入規定	改列輸入規定
2937.12.00.00-0	胰島素及其鹽類 Insulin and its salts	808	835*
2937.21.20.00-5	氫化可體松 Hydrocortisone	808	835*
2937.90.00.20-1	胺基酸衍生物 Amino-acid derivatives	808	835*
2937.90.00.90-6	其他天然或以合成方法再製之荷爾蒙；及其主要用作荷爾蒙之衍生物及結構式類似物 Other hormones, natural or reproduced by synthesis; derivatives and structural analogues thereof	808	835*
2942.00.10.00-5	供合成原料藥、動物用藥及輔助飼料藥之化學產品 Chemicals, used for manufacturing of pharmaceutical, veterinary medicines	818	804
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	808 B01	835* B01
3002.10.00.19-9	其他血清 Other sera	808 B01 MP1	835* B01 MP1
3003.90.99.10-2	抗過敏抗組織胺用藥 Drugs for antihypersensitivity and antihistamine	818 MW0	804 MW0

3003.90.99.90-5	其他醫藥製劑（不包括第3002、3005或3006節所列者），包含兩種或以上之成分業經混合供治療或預防疾病之用，不具有劑量或零售包裝式樣者 Other medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale	818 MP1	804 MP1
3004.90.91.00-1	抗排斥醫藥製劑 Immunosuppressive preparations	818	804
3004.90.99.10-1	抗過敏抗組織胺用藥 Drugs for antihypersensitivity and antihistamine	818	804
3004.90.99.90-4	其他醫藥製劑（不包括第3002、3005或3006節所列者）包含經混合或未混合產品供治療或預防疾病用，具有劑量（包括經皮給藥形態者）或零售包裝式樣者 Other medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale	818 MP1	804 MP1

號列項數: 12

輸入規定代號說明

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准許（免除簽發許可證）。

Import permitted (free from licensing)

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。
- 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.
- 504 一、進口人用醫療器材應依下列規定辦理：（一）應檢附衛生福利部核發之醫療器材許可證影本或同意文件，並應申報填列醫療器材許可證號碼（十四碼）。（二）如屬危險性醫療儀器，除應檢附衛生福利部核發之醫療器材許可證影本，及申報填列醫療器材許可證號碼（十四碼）外，並須檢附衛生福利部核准醫療機構購置之同意文件。二、非供人用者免依上述規定辦理。
1. Importation of medical devices for human use must be handled according to the following regulations: (1) A photocopy of the medical devices pre-marketing license or an approval document issued by the Ministry of Health and Welfare should be submitted. In addition, the number of the pre-marketing license (consisting of 14 letters and digits) must be declared and listed in the import declaration . (2) If the medical devices being imported are dangerous, then besides the photocopy of the medical device pre-marketing license and the license number declared and listed in the import declaration, an approval of the medical institutions/facilities procurement from the Ministry of Health and Welfare is also required. 2. Importation of medical devices which are not for human use are exempted from the above regulations.

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）進口人用之藥品（包括製劑、原料藥、助診藥類及生物製劑），如屬專供研究及實驗使用者，應憑衛生福利部核發之同意文件（帶有 1 4 碼之簽審文件號碼）通關放行。

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)Importation of drugs (including pharmaceutical products, active pharmaceutical ingredients, diagnostics and biological products) for research or experimental study use, an approval (having the special 14 codes on the import application) issued by the Ministry of Health and Welfare is required for customs clearance.

508 一、進口食品添加物應依下列規定辦理：（一）輸入衛生福利部發布「食品添加物使用範圍及限量暨規格標準」收載之單方食品添加物（香料除外），應檢附衛生福利部核發之食品添加物許可證影本，並依 F 0 1 規定辦理。（二）如屬香料或複方食品添加物，應依 F 0 1 規定辦理。二、進口非食品添加物之食品原料，應依 F 0 1 規定辦理。三、如屬食品添加物之樣品、贈品，應檢附衛生福利部核發之「貨品進口同意書申請書（食品、添加物樣品）」。四、進口非供食品或食品添加物用途者，於進口報單填列專用代碼 D H 9 9 9 9 9 9 9 9 5 0 8，免依上述規定辦理。

1. For importation of food additives must be handled according to the following regulations: (1) If the petitioned food additive (excluding flavorings) is a single chemical enlist in the current "Standards for Specification, Scope, Application and Limitation of Food Additives", a photocopy of the food additives license issued by the Ministry of Health and Welfare is required, and shall be governed by the regulation of "F01". (2) For importation of flavorings or food additive mixtures, shall be governed by the regulation of "F01". 2. For importation of foods but not food additives, shall be governed by the regulation of "F01". 3. If the imported food additives and it is samples or gifts, a " application import certificate" issued by the Ministry of Health and Welfare is required. 4. Importation of commodity not to be used as foods or food additives, should list the special code DH99999999508 on the import application and is exempted from the above regulations.

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(一) 進口人用藥品，應依 5 0 3 規定辦理 (二) 進口人用醫療器材，應依 5 0 4 規定辦理。(三) 進口動物用藥品，應依 4 0 6 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、人用醫療器材、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 "503". (2) Importation of medical devices for human use is governed by the regulation of "504" (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, medical devices for human use and veterinary medicines" is required.

808

(一) 進口人用藥品，應依 5 0 6 規定辦理。(二) 進口動物用藥品，應依 4 0 6 規定辦理。(三) 進口食品及食品添加物，應依 5 0 8 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、動物用藥品、食品及食品添加物」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 food and food additives is governed by the regulation of "508".(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 use, veterinary medicines, food and food additives" is required.

818

(一) 進口人用藥品，應依 5 0 3 規定辦理。(二) 進口動物用藥品，應依 4 0 6 規定辦理。(三) 進口食品添加物，應依 5 0 8 規定辦理。(四) 進口醫療器材，應依 5 0 4 規定辦理。(五) 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、食品添加物、醫療器材」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 food additives is governed by the regulation of "508".(4) Importation of medical equipment is governed by the regulation of "504".(5) 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, food additives and medical equipment" is required.

- 835* (一) 進口人用藥品，應依 5 0 6 規定辦理 (二) 進口動物用藥品，應依 4 0 6 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.
- 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.
- MP1 (一) 大陸物品有條件准許輸入，應符合「大陸物品有條件准許輸入項目、輸入管理法規彙總表」之規定。(二) 「大陸物品有條件准許輸入項目、輸入管理法規彙總表」內列有特別規定「M X X」代號者，應向國際貿易局辦理輸入許可證；未列有特別規定「M X X」代號者，依一般簽證規定辦理。

(1) Importation of Mainland China products in this category is conditionally permitted. The importation should conform to the regulations of "Consolidated List of Conditional Import Items of Mainland China Origin and Regulations Governing Import of Mainland China Origin Commodities".(2) Importation of items on the "Consolidated List of Conditional Import Items of Mainland China Origin and Regulations Governing Import of Mainland China Origin Commodities" with "MXX" code requires Import Permit issued by the BOFT; Importation of items without "MXX" code shall be subject to the general code of import permit issuance.

MW0

大陸物品不准輸入。

Importation of Mainland China products is prohibited.

F01

輸入商品應依照「食品及相關產品輸入查驗辦法」規定，向衛生福利部食品藥物管理署申請辦理輸入查驗。【註：相關規定應洽衛生福利部食品藥物管理署】。

Importation of foods shall follow the "Regulations for Inspection of imported Foods and Related Products".The importer shall apply for inspection to the Food and Drug Administration,Ministry of Health and Welfare(FDA).(Note:Please contact FDA for relevant inspection requirements of food imports.)