

## Details of Amendments of Import Regulations

CCC Code	Description of Goods	Original Import Regulation	Amended Import Regulation
1905.90.10.00-3	Empty cachets of a kind suitable for pharmaceutical use	821	821*
2934.99.90.90-1	Other heterocyclic compounds	508	847
2937.12.00.00-0	Insulin and its salts	835	835*
2937.21.20.00-5	Hydrocortisone	835	835*
2937.90.00.20-1	Amino-acid derivatives	835	835*
2937.90.00.90-6	Other hormones, natural or reproduced by synthesis; derivatives and structural analogues thereof	835	835*
3001.90.40.90-7	Other glands and other organs, dried, whether or not powdered	821	821*
3001.90.90.00-5	Other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included	842	842*
3002.12.00.19-7	Other sera	B01	B01
		835	835*
		B01	B01
		MP1	MP1
3002.12.00.20-4	Plasma	821	821*
		B01	B01
		MP1	MP1
3002.12.00.90-9	other blood fractions	823	823*
		B01	B01
		MP1	MP1
3002.13.00.00-7	Immunological products, unmixed, not put up in measured doses or in forms or packings for retail sale	823	823*
		MP1	MP1
3002.14.00.00-6	Immunological products, mixed, not put up in measured doses or in forms or packings for retail sale	823	823*
		MP1	MP1
3002.15.00.90-6	Other immunological products, put up in measured doses or in forms or packings for retail sale	823	823*
		MP1	MP1
3002.49.00.90-6	Toxins, cultures of micro-organisms (excluding yeasts) and similar products	824	824*
		B01	B01
		MW0	MW0
3002.59.00.00-2	Other Cell cultures , whether or not modified	824	824*
		MW0	MW0
3002.90.00.91-3	Other articles of heading 3002	824	824*
		B01	B01
		MW0	MW0
9602.00.41.00-5	Capsules for pharmaceutical products	821	821*

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Import Code	Code Explanation
(Blank)	Import permitted (free from licensing)
406	For importation of veterinary drugs (including raw material pharmaceutical products, pharmaceutical products, and biological products): (1) a) A "veterinary drug dealer license" and a "veterinary drug import license" (non-licensed importers shall be authorized by the license holder) issued by the Ministry of Agriculture , are prerequisite; or b) if the imported goods are raw (bulk) materials limited to the self-use of veterinary drug manufacturer, a "license for manufacturing veterinary drug " containing the active ingredient(s) issued by the Ministry of Agriculture and an "Import Certificate For Raw (Bulk) Material Limited to The Veterinary Drug Manufacturer for Self-use " issued by the Animal and Plant Health Inspection Agency, Ministry of Agriculture are prerequisite. 2) If the imported goods are samples or gifts, an "Import Certificate for Veterinary Drug Samples or Gifts" issued by the Animal and Plant Health Inspection Agency, Ministry of Agriculture is prerequisite.
501	Approval from the Ministry of Health and Welfare is required.
502	For importing dry goods:(1) A photocopy of business license for dealing with Chinese medicine ( or pharmaceutical manufacturing license issued by the Ministry of Health and Welfare ) is required.(2) Importing powder goods should be attached a photocopy of the drug license issued by the Ministry of Health and Welfare, or an approval document issued by the Ministry of Health and Welfare.(3) Commodity description shall indicate the specific name in Chinese and Chinese medicine materials or Chinese medicine powder.The above regulations do not apply to importing non-dry goods.
503	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	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	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.

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508	1. For importation of food additives must be handled according to the following regulations: (1) If the petitioned food additive (excluding flavorings) is enlist in the current "Standards for Specification, Scope, Application and Limitation of Food Additives", a food additives license approval from 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 are samples or gifts, an "import certificate" approval from 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.
821	(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.
821*	(1) Importation of medicines for human use is governed by the regulation of "503". (2) Importation of veterinary drugs 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 specimens of communicable diseases or suspected specimens of communicable diseases for testing is governed by the regulation of "501". (5) Importation of commodities not belonging to the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as human medicine or veterinary drug, foods and food-relevant products, and is not a specimen of communicable diseases or a suspected specimen of communicable diseases" is required.
823	(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 medical equipment is governed by the regulation of "504". (4) Importation of foods and food-relevant products is governed by the regulation of "F01". (5) 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, medical equipment, foods and food-relevant products" is required.
823*	(1) Importation of medicines for human use is governed by the regulation of "506". (2) Importation of veterinary drugs is governed by the regulation of "406". (3) Importation of medical equipment is governed by the regulation of "504". (4) Importation of foods and food-relevant products is governed by the regulation of "F01". (5) Importation of specimens of communicable diseases or suspected specimens of communicable diseases for testing is governed by the regulation of "501". (6) Importation of commodities not belonging to the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as human medicine or veterinary drug, medical equipment, foods and food-relevant products, and is not a specimen of communicable diseases or a suspected specimen of communicable diseases" is required.

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824	<p>1.Imported human drug products, human blood: (1) is governed by regulation "506". (2) The dedicated code (number) of import declaration (application for import) for imported non-infectious human blood for research, teaching or testing is DHM9999999990. 2. Importation of veterinary medicines is governed by the regulation of "406". 3. Importation of medical equipment is governed by the regulation of "504".4.Importation of infectious biological materials for experimental study (except for foods and food-relevant products) is governed by the regulation of "501". 5 .Importation of foods and food-relevant products is governed by the regulation of "F01". 6.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, medical equipment, infectious biological materials for experimental study, foods and food-relevant products" is required.</p>
824*	<p>1. Imported human drug products and human blood: (1) is governed by the regulation of "506". (2) The dedicated code (number) of import declaration (application for import) for imported non-infectious human blood for research, teaching or testing is DHM9999999990. 2. Importation of veterinary drugs is governed by the regulation of "406". 3. Importation of medical equipment is governed by the regulation of "504". 4. Importation of infectious biological materials for experimental study (except for foods and food-relevant products) is governed by the regulation of "501". 5. Importation of foods and food-relevant products is governed by the regulation of "F01". 6. Importation of human cell lines: (1) is governed by the regulation of "501". (2) Importation of human cell lines (including human stem cell lines, human embryonic stem cell lines) for research should list the special code DHK9999999999 on the import declaration. 7. Importation of commodities not belonging to the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as human medicine or veterinary drug, medical equipment, infectious biological materials for experimental study, foods and food-relevant products, and is not a human cell line" is required.</p>
835	<p>(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.</p>
835*	<p>(1) Importation of medicines for human use is governed by the regulation of "506". (2) Importation of veterinary drugs is governed by the regulation of "406". (3) Importation of specimens of communicable diseases or suspected specimens of communicable diseases for testing is governed by the regulation of "501". (4) Importation of commodities not belonging to the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as human medicine or veterinary drug, and is not a specimen of communicable diseases or a suspected specimen of communicable diseases" is required.</p>

## Details of Amendments of Import Regulations

Import Code	Code Explanation
842	1.Imported human drug products, human specimens: (1) is governed by regulation "506". (2) The dedicated code (number) of import declaration (application for import) for imported non-infectious human specimens for research, teaching or testing is DHM9999999999. 2. Importation of human cell lines: (1) is governed by regulation " 501". (2) Importation of human cell lines (including human stem cell lines, human embryonic stem cell lines) for research should list the special code DHK9999999999 on the import application. 3. Importation of veterinary medicines is governed by regulation "406". 4. Importation of Chinese medicine materials shall comply with the regulation of "502". 5 Importation of commodities not belonging to the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as human medicine or veterinary medicine, and is not a human cell line or a specimen of human or animal origin or Chinese medicine materials" is required.
842*	1. Imported human drug products, human specimens: (1) is governed by the regulation of "506". (2) The dedicated code (number) of import declaration (application for import) for imported non-infectious human specimens for research, teaching or testing is DHM9999999999. 2. Importation of veterinary drugs is governed by the regulation of "406". 3. Importation of Chinese medicine materials shall comply with the regulation of "502". 4. Importation of specimens of communicable diseases or suspected specimens of communicable diseases for testing is governed by the regulation of "501". 5. Importation of commodities not belonging to the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as human medicine or veterinary drug, and is not a specimen of human or animal origin, Chinese medicine materials, a specimen of communicable diseases or a suspected specimen of communicable diseases" is required.
847	(1) Importation of food additives is governed by the regulation of "508". (2) Importation of infectious biological materials for experimental study (except for foods and food-relevant products) is governed by the regulation of "501". (3) Importation of commodities not belonging to the aforesaid items shall be exempted from the aforesaid regulations, but a clear indication that the commodity is "not to be used as food additives and infectious biological materials for experimental study" is required.
B01	Importation shall be subject to the prescription set forth in the "List of Items Subject to Animal & Plant Quarantine" and relevant quarantine requirements compiled by the Animal and Plant Health Inspection Agency, Ministry of Agriculture.
F01	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).
MP1	(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 International Trade Administration; Importation of items without "MXX" code shall be subject to the general code of import permit issuance.
MW0	Importation of Mainland China products is prohibited.