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Measures for the Administration of Imported Medicinal Materials (for Trial Implementation)

进口药材管理办法（试行）

Issued By	**State Food and Drug Administration**
Subject	**Others Provisions**
Promulgated on	**November 24th 2005**
Effective from	**February 1st 2006**
Source	**www.sda.gov.cn**

For the purpose of strengthening the supervision and administration of imported medicinal materials and guaranteeing the quality of imported medicinal materials, State Food and Drug Administration issued Measures for the Administration of Imported Medicinal Materials (for Trial Implementation) (hereinafter referred to as "the Measures") on November 24th 2005. The Measures shall apply to the application for, the examination and approval of, and the registration, archival filing, port inspection, supervision and administration of imported medicinal materials.

According to the Measures, Medicinal materials must be imported via the ports permitting the import of drugs as approved by the State Council or the border ports permitting the import of medicinal materials as approved by the State Council. A border port permitting the import of medicinal materials may only import medicinal materials produced in its neighbouring countries or regions. State Food and Drug Administration (hereinafter referred to as SFDA) shall take charge of the examination and approval of the import of medicinal materials, and shall supervise and administer the registration, archival filing, and port inspection, etc. The (food) drug administration of each province, autonomous region, or municipality directly under the Central Government shall supervise and administer imported medicinal materials. The (food) drug administration at the locality of a port permitting the import of drugs or a border port permitting the import of medicinal materials (hereinafter referred to as the port or border port (food) drug administration) shall take charge of the registration and archival filing of imported medicinal materials, organize port inspections, and conduct supervision and administration. The National Institute for the Control of Pharmaceutical and Biological Products shall take charge of the sample inspection, re-check of quality standards, etc. of the initially imported medicinal materials. The drug inspection institutions as determined by SFDA shall take charge of the port inspection of imported medicinal materials.

As to the actual procedures of the importation of medicinal materials, the Measures lists the following steps:

1. An applicant shall fill out an "Application Form for Import of Medicinal Materials" and submit the relevant documents to the SFDA. The SFDA shall, within 30 days after receipt of the application documents, finish the technical review and administrative examination, and shall issue an "Approval Document for Import of Medicinal Materials" if the application is qualified, or issue a "Notification Document on the Examination Opinions" and explain the reasons therefore if the application is unqualified.
2. An applicant shall, after obtaining the "Approval Document for Import of Medicinal Materials", organize the import of medicinal materials at the port of arrival as indicated in the "Approval Document for Import of Medicinal Materials", have the documents registered and archived in the port or border port (food) drug administration, fill out a "Report List for Inspection of the Imported Medicinal Materials", and submit the relevant documents. The port or border port (food) drug administration shall examine the completeness, regularity and authenticity of the registered and archived documents, and make an examination decision on the very day. If the documents are qualified, it shall issue a "List of Customs Clearance of the Imported Drugs", and send a "Notification for Port Inspection of Imported Medicinal Materials" to the drug inspection institution determined by the SFDA.
3. The drug inspection institution determined by the SFDA shall, within 2 days after receipt of the "Notification for Port Inspection of Imported Medicinal Materials", make a on-site sampling at the prescribed place for deposit of goods, and shall finish the inspection within 20 days after the sampling, issue an "Inspection Report on the Imported Medicinal Materials", submit it to the local port or border port (food) drug administration, and notify the applicant.

According to the Measures, the packing of imported medicinal materials must meet the quality requirements for imported medicinal materials, and be convenient for storage, transport and import inspection. On the package of each piece of goods, the Chinese name of the medicinal materials, the approval document number, the place of origin, the shipping mark, the name of the applying enterprise, the name of the exporter, the port of arrival, the weight and the date of processing and that of packing, etc. must be indicated.

The Measures shall come into force on February 1st 2006. Where any relevant provisions on imported medicinal materials, which were promulgated before the Measures come into force, are inconsistent with the Measures, they shall be stopped from implementation as of the date when the Measures come into force.

Provisions on Archival Administration of Drugs Processed upon Entrustment of Overseas Pharmaceutical Manufacturers

接受境外制药厂商委托加工药品备案管理规定

Issued By	**State Food and Drug Administration**
Subject	**Others Provisions**
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Source	**www.sda.gov.cn**

In accordance with the provisions of Article 37 of the Provisions on Supervision and Administration of Pharmaceutical Manufacturing, State Food and Drug Administration issued Provisions on Archival Administration of Drugs Processed upon Entrustment of Overseas Pharmaceutical Manufacturers (hereinafter referred to as "the Provisions") on November 15th 2005 so as to regulate the archival administration of drugs processed upon entrustment of overseas pharmaceutical manufacturers.

According to the Provisions, "to process drugs upon entrustment of overseas pharmaceutical manufacturers" shall mean that domestic pharmaceutical manufacturing enterprises are entrusted by overseas pharmaceutical manufacturers to process drugs, and the processed drugs shall not be sold or used inside the territory of China. An entrusting party shall be a pharmaceutical manufacturer holding the permit for marketing or selling the processed drug abroad or be its authorized agent. An entrusted party shall be a domestic pharmaceutical manufacturing enterprise holding a "Certificate of Good Manufacturing Practices for Human Drugs" suitable for the manufacturing conditions of this processed drug.

Both parties to the entrustment shall sign a contract on processing the drug upon entrustment, with the contents clearly indicating the rights, obligations and legal liabilities, etc. of both parties. The entrusting party shall be responsible for the quality of the drug. An entrusted pharmaceutical manufacturing enterprise shall, within 30 days as of signing the processing contract, fill out the "Archival Filing Form on Processing Drugs upon Entrustment of an Overseas Pharmaceutical Manufacturer" and the "Letter of Commitment", submit them to the food and drug administrative bureau of the province, autonomous region, and municipality directly under the Central Government where it is located for archival filing. The entrusted pharmaceutical manufacturing enterprise may not manufacture the drug until the documents have been archived.

According to the Provisions, no import registration or import archival filing procedure is required for the raw materials, bulk preparations, subsidiary materials and packing

materials, etc. coming from abroad and needed in processing drugs, nor shall they be assigned in any form for use or be used to manufacture domestically sold drugs.

Official Reply of the State Administration of Taxation on the Tax Refund to Small-scale Taxpayer Foreign-funded Enterprises for Their Purchase of Home Equipments

关于小规模纳税人外商投资企业采购国产设备退税问题的批复

Issued By	**State Administration of Taxation**
Subject	**Tax Refund**
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Source	**www.chinatax.gov.cn**

The State Administration of Taxation replied to Qingdao Municipal Bureau of National Taxes on the relevant issues on the tax refund to small-scale taxpayer Foreign-funded Enterprises for their purchase of home equipments.

According to the reply, as the anti-forgery VAT tax-control certification system is unable to certify the special VAT invoices for small-scale taxpayers, before the anti-forgery VAT tax-control certification system is enabled to certify the special VAT invoices for small-scale taxpayers, Qingdao Municipal Bureau of National Taxes may, on the condition of confirming through investigation by letter that the special VAT invoices obtained by the small-scale taxpayer foreign-funded enterprises under its jurisdiction, who have purchased domestically produced equipment, are inerrable, handle the tax refund matters in accordance with the presently applicable provisions on tax refund for export.

Wenger & Vieli, Beijing, January 21st 2006

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