Appendix 1: Table of information required for making changes in items of registered pursuant to medicinal product manufacturing licenses and approval document showing conformity with the Pharmaceutical Good Manufacturing Practice Regulations

I. Western medicinal products
1. The following documents shall be submitted when applying for changing the manufacturer's name in the "manufacturing license for domestically produced medicinal products":
(1) A photocopy of the original manufacturing license for domestically produced medicinal products.
(2) Evidentiary documents showing the manufacturer's change of registration.
(3) A photocopy of the pharmaceutical firm license.
2. The following application documents shall be submitted when applying to change the full-time resident pharmacist serving as manufacturing supervisor pursuant to a "manufacturing license for domestically produced medicinal products":
(1) A photocopy of the original manufacturing license for domestically produced medicinal products.
(2) A photocopy of the pharmaceutical firm license.
3. The following application documents shall be submitted when applying for a change in the manufacturer's name or address (address plate renumbering only) in the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations":
(1) An application for amendment of registration.
(2) A photocopy of the original approval document showing conformity with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) The original of the letter detailing the items changed by the foreign manufacturer.
(4) The official evidentiary document issued by the competent authority of the country of manufacturing for the change of name or address by the foreign manufacturer, or a photocopy of the documents certified by an overseas representative office of the ROC.
4. The following application documents shall be submitted when applying for a transfer of the agent's rights of the importing pharmaceutical firm in the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations":
(1) An application for amendment of registration.
(2) A photocopy of the original approval document showing conformity with thePharmaceutical Good Manufacturing Practice Regulations.
(3) Photocopies of the pharmaceutical firm licenses of the assignor and the assignee.
(4) The original of the assignment agreement between the two parties, stamped with the seals of both the assignor and the assignee.
(5) The original of the foreign manufacturer's power of attorney, showing that the assignor's agent rights have been terminated and have been obtained by the assignee, along with the addresses of each party and the content of matters relating to approval of the transfer; the power of attorney must be certified by an overseas representative office of the ROC.
5. The following documents shall be submitted when applying for a change in the name of the importing pharmaceutical firm in the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations" (not involving a transfer of agent rights):

(1) An application for amendment of registration.
(2) Photocopies of the approval document showing conformity with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) A photocopy of the pharmaceutical firm license.
(4) The competent health authority's letter of consent to the change.
6. The following documents shall be submitted when applying for a change in the name of the items approved (changes in product names only; other content remains unchanged) in the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations ":
(1) An application for amendment of registration.
(2) A photocopy of the original approval document showing conformity with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) The original of the letter explaining the items changed by the foreign manufacturer.
(4) The official evidentiary document issued by the competent authority of the country of manufacturing for the change of name of the product, or a photocopy of the evidentiary document certified by an overseas representative office of the ROC.
7. When applying for relocation of the manufacturing plant or for amendment of any license/approval item or operations content specified in the "Manufacturing **license for domestically produced medicinal products" or "Approval document for a foreign manufacturer of imported medicinal products in conformity with the Pharmaceutical Good Manufacturing Practice Regulations," the application documents required to be submitted shall be done as specified in the** Regulations of Medicament Manufacturer Inspection.
II. Chinese herbal medicine products
1. The following application documents shall be submitted when applying for a change in the name of a manufacturer of domestically produced medicinal products in a "manufacturing license for domestically produced medicinal products":
(1) An application for amendment of registration.
(2) The original copy of the original manufacturing license for domestically produced medicinal products.
(3) A photocopy of the pharmaceutical firm license.
2. The following application documents shall be submitted when applying for a change in the full-time resident pharmacist serving as manufacturing supervisor pursuant to a "manufacturing license for domestically produced medicinal products":
(1) An application for amendment of registration.
(2) The original of the manufacturing license originally obtained for domestically produced medicinal products.
(3) A photocopy of the pharmaceutical firm license.
3. The following application documents shall be submitted when applying for a change in the manufacturer's name or address (address plate renumbering only) in the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations":
(1) An application for amendment of registration.
(2) A photocopy of the original approval document showing conformity with the Pharmaceutical Good Manufacturing Practice Regulations.

(3) The original of the letter detailing the items changed by the foreign manufacturer.
(4) The official evidentiary document issued by the competent authority of the country of manufacturing for the change of name or address by the foreign manufacturer, or a photocopy of the evidentiary document certified by an overseas representative office of the ROC.
4. The following application documents shall be submitted when applying for a transfer of the agent's rights of the importing pharmaceutical firm in the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations":
(1) An application for amendment of registration.
(2) A photocopy of the original approval document showing conformity with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) Photocopies of the pharmaceutical firm licenses of the assignor and the assignee.
(4) The original of the assignment agreement between the two parties, stamped with the seals of both the assignor and the assignee.
(5) The original of the foreign manufacturer's power of attorney, showing that the assignor's agent rights have been terminated and have been obtained by the assignee, along with the addresses of each party and the content of matters relating to approval of the transfer; the power of attorney must be certified by an overseas representative office of the ROC.
5. The following documents shall be submitted when applying for a change in the name of the importing pharmaceutical firm in the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations" (not involving a transfer of agent rights):
(1) An application for amendment of registration.
(2) Photocopies of the approval document showing conformity with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) A photocopy of the pharmaceutical firm license.
(4) The competent health authority's letter of consent to the change.
6. The following documents shall be submitted when applying for a change in the name of the items approved in the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations" (for a change of product name only; other content remains unchanged):
(1) An application for amendment of registration.
(2) A photocopy of the original approval document showing conformity with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) The original of the letter detailing the changes made by the foreign manufacturer.
(4) The official evidentiary document issued by the competent authority of the country of manufacturing for the change of name of the product, or a photocopy of the evidentiary document certified by an overseas representative office of the ROC.
7. When applying for relocation of the manufacturing plant or for amendment of any license/approval item or operations content specified in the "manufacturing license for domestically produced medicinal products" or the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations," the application documents required to be submitted shall be as specified in the Regulations of Medicament Manufacturer Inspection.
III. Medical devices

1. The following application documents shall be submitted when applying for a change in the manufacturer's name (with no change in address) for a "manufacturing license for domestically produced medical devices":
(1) An application for amendment of registration.
(2) The original of the manufacturing license for domestically produced medical devices.
(3) A photocopy of the pharmaceutical firm license.
2.The following application documents shall be submitted when applying to change the management representative of "Manufacturing license for domestically produced medical devices":
(1) An application for amendment of registration.
(2) The original of the manufacturing license for domestically produced medical devices.
(3) The original manufacturer's evidentiary document showing appointment of the management representative.
3. The following application documents shall be submitted when applying for a change in the manufacturer's name (with no change of address) with respect to an "approval document showing conformity by a foreign manufacturer of imported devices with the Pharmaceutical Good Manufacturing Practice Regulations":
(1) An application for amendment of registration.
(2) The original of the approval document showing conformity by the foreign manufacturer of imported medical devices with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) The original of the letter of notification issued for a change in the manufacturer's name.
(4) The original of the evidentiary document issued by the highest competent health authority of the country of original manufacture showing the change of name (with no change in address) by the manufacturer or the original of the free sale certificate, certified by an overseas representative office of the ROC, with a period of validity of 2 years.
4. The following application documents shall be submitted when applying for a change in the manufacturer's address (address plate renumbering only) in the "approval document showing conformity by a foreign manufacturer of imported medical devices with the Pharmaceutical Good Manufacturing Practice Regulations":
(1) An application for amendment of registration.
(2) The original of the approval document showing conformity by the foreign manufacturer of imported medical devices with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) The original of the original manufacturer's letter of notification of a change of address.
(4) The evidentiary documents issued by the household/business registration agency or related official agency of the original manufacturer's home country.
5. The following application documents shall be submitted when applying for a transfer of the agent's rights held by the importing pharmaceutical firm in the "approval document showing conformity by a foreign manufacturer of imported devices with the Pharmaceutical Good Manufacturing Practice Regulations":
(1) An application for amendment of registration (shall be completed jointly by both parties to the transfer).
(2) The original of the approval document showing conformity by a foreign manufacturer of imported devices with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) The original of the assignment agreement issued by the pharmaceutical firm for assignment of the approval document showing conformity by the foreign manufacturer of

imported medical devices with the Pharmaceutical Good Manufacturing Practice Regulations.
(4) The original of the registration document showing the original manufacturer's authorization (must show the details of the termination of the registration of the first pharmaceutical firm's authorization and the subsequent authorization and registration of the second pharmaceutical firm; the matters authorized and the addresses of the first and second pharmaceutical firms shall be included and the documents must be certified by an overseas representative office of the ROC, with a period of validity of 1 year).
6. The following application documents shall be submitted when applying for a change in the name of the pharmaceutical firm holding the "approval document showing conformity by a foreign manufacturer of imported medical devices with the Pharmaceutical Good Manufacturing Practice Regulations" (not involving a transfer of agent rights):
(1) An application for amendment of registration.
(2) The original of the approval document showing conformity by the foreign manufacturer of imported medical devices with the Pharmaceutical Good Manufacturing Practice Regulations.
(3) A photocopy of the pharmaceutical firm license.
7. When applying for relocation of the manufacturing plant or for amendment of any license/approval item or operations content specified in the "manufacturing license for domestically produced medicinal products" or the "approval document showing conformity by a foreign manufacturer of imported medicinal products with the Pharmaceutical Good Manufacturing Practice Regulations," the application documents required to be submitted shall be as specified in the Regulations of Medicament Manufacturer Inspection.