Guidelines for Registration of Medical Devices (revised April 12, 2006)

Chapter 1 General Principles

Article 1 These Guidelines are formulated in accordance with the regulations of Article 40, Paragraph 3 of the Pharmaceutical Affairs Act (herein referred to as this Act).

Article 2 Changes, transfer, extension of registration, re-issuance of damages, and replacement of losses for the registration and market approval and permit license of medical devices shall follow regulations of this set of Guidelines. Matters not regulated in these Guidelines shall be handled in accordance with other relevant laws and regulations and regulations announced by the central competent health authority.

Article 3 When applying for registration of any item in the foregoing Article, review fees shall be paid, and application forms produced by the central competent health authority shall be filled out, and shall be submitted together with information required to be attached by regulations of these Guidelines to the central competent health authority for review.

The application forms referred to in the foregoing Paragraph include application form for the registration and market approval of medical devices, application form for change of registration, application form for extension of permit license validity, affidavit, form for attaching outer box instruction label, form for attaching license, and other form and document formats associated with application procedures.

Article 4 When an application has passed documentary review, the applicant shall, in accordance with the permit license collection notice, pay the permit license fee, and collect the license by the designated deadline.

For medical device requiring testing, the applicant shall, in accordance with the testing notice, pay the testing fee by the designated deadline, and submit for testing a sufficient amount of samples needed for testing.

The central competent health authority may, for need for emergency care of the public, issue a temporary license document valid for a half-year.

Article 5 An shall not be approved in any of the following situations:

1. Fees have not been paid in accordance with regulations, or attached materials are incomplete, or are inconsistent with the contents of the application.
2. The applicant has failed to collect the permit license or to submit samples

for testing by the designated deadline, or the samples submitted for testing do not meet requirements.

3. The applicant has failed to publish, revise, or change the packaging, labels, or instructions for the medical devices in accordance with regulations.
4. The medical device under application is considered to be hazardous to human health, or raises safety, quality, or efficacy concerns.
5. Other situations not complying with these Guidelines or relevant laws and regulations, or not complying with regulations announced by the central competent health authority.

Article 6 When an application fails to comply with regulations and must be corrected, the applicant shall make correction by the deadline designated by the central competent health authority. The correction deadline shall be two months.

If the applicant cannot make correction by the deadline, the applicant may apply before the deadline to the central competent health authority for a one-month extension; such extension shall be granted only once.

If the applicant fails to make correction before the deadline, or fails to make correction before the expiration of the one-month extension period, the central competent health authority may perform review on the basis of existing information and accept or reject the application.

Article 7 The manufacturing and sales approval certificates of the country of origin referred to in this set of Guidelines are verifying documents issued by the highest health authority in the country where the imported device is manufactured. The content of such documents shall state the name of the manufacturing plant, the plant location, the name, specifications, and model of the medical device, the circumstances of manufacture, and confirmation of approval of domestic sale in that country. If it is confirmed that the medical device in question is not regulated by the highest health authority in the country of manufacture, said manufacturing and sales approval documents may be issued by the local health agency or an organization approved by Taiwan's central competent health authority.

With regard to the manufacturing and sales approval documents in the foregoing Paragraph, if the manufacture of an imported medical device is entrusted, and the device is not on sale in the country of the entrusted manufacturing plant, proof of free sale from the country of the entrusted company and proof of manufacture from the entrusted manufacturing plant may be submitted instead of the foregoing manufacturing and sales approval documents.

The verifying documents in the above two Paragraphs shall remain valid for

two years after the date of issuance, and shall be notarized by Taiwan's embassy or consulate, representative office, other official office, or overseas organization in that country authorized by the Ministry of Foreign Affairs (hereafter referred to as the overseas representative organization of Taiwan). A Chinese or English translation shall be attached when the verifying documents are not in English, and the translation shall also be notarized.

Article 8 The authorization registration of the overseas original manufacturer referred to in these Guidelines consists of authorized agent verification documents issued by the original manufacturer of the imported medical device, and shall comply with the following regulations:

1. The content shall explicitly state that the original manufacturer authorizes an agent in Taiwan to apply for registration and market approval, and shall specify the commissioned or authorized drug company's name and address, and the name, specifications, and model of the medical device.
2. The authorization registration of the overseas original manufacturer shall remain valid for one year after the date of issuance. A Chinese or English translation shall be attached when the verifying documents are not in English.

The authorization registration of the overseas original manufacturer in the foregoing Paragraph may be replaced by the following documents:

1. Authorization registration verifying documents submitted by a parent company wishing to import a medical device; the content of the authorization to apply for registration shall explicitly state the name and address of the manufacturing plant, and shall specify the commissioned or authorized pharmaceutical company's name and address, and the name, specifications, and model of the medical device.
2. Verifying documents submitted by the original manufacturer of the imported medical device and explaining its foreign agent, plus authorized agent verification documents submitted by the foreign agent and the authorization to apply for registration of the authorized agent in Taiwan; the latter document shall specify the commissioned or authorized pharmaceutical company's name and address, and the name, specifications, and model of the medical device.

The replacement documents in the foregoing Paragraph shall remain valid for one year after the date of issuance. A Chinese or English translation shall be attached when the verifying documents are not in English.

Article 9 The in vitro diagnostic devices (IVD) referred to in these Guidelines are medical devices such as diagnostic reagents, instruments or systems used to

collect, prepare, and test specimens from human body in order to diagnose disease or other conditions (such as status of health).

Article 10 The level 1, level 2, and level 3 medical devices mentioned in these Guidelines are determined in accordance with the grading regulations in the Regulations Governing Management of Medical Devices.

Article 11 When applying for registration and market approval, change of registration, or extension of permit license validity for a medical device using cow or sheep/goat tissue, there shall be attached an explanation of animal raw material source control procedures and proof of raw material source from the original manufacturer in order to verify that the processes connected with the medical device and the ultimate finished product do not use any cow or sheep/goat products from bovine spongiform encephalopathy (BSE) epidemic areas announced by the Council of Agriculture, Executive Yuan, and have not been contaminated by BSE pathogens.

The foregoing restriction shall not apply when the central competent health authority, after consulting international management regulations concerning cow/sheep/goat tissue, has announced on the basis of risk that cow/sheep/goat tissue is contaminated by BSE pathogens that the materials in the foregoing Paragraph do not need to be attached.

Chapter 2 Registration and Market Approval

Article 12 For application for registration and market approval, except where otherwise regulated, review of testing specifications, sending for testing, and technical documentary tasks shall be performed simultaneously.

The operating procedures in the foregoing Paragraph shall be performed in accordance with the announcements of the central competent health authority.

Article 13 Application for registration and market approval, after passing the documentary review and a permit license collected, if the applicant has failed to comply with sending for testing procedures, or if samples sent for testing have failed to meet requirements, the applicant must return the permit license to the central competent health authority within ten days of notification, and the case shall be handled in accordance with the announced regulations in the second Paragraph of the foregoing Article.

Article 14 For application for registration and market approval for domestically manufactured level 1 medical devices, the following documents shall be attached:

1. Original copies of registration and market approval application and

affidavit for level 1 medical device.

2. Photocopy of permit license of pharmaceutical firms for medical device manufacturing affixed or stapled to license attachment form.

When the medical device under application for registration and market approval is entrusted for manufacturing or testing, it shall comply with regulations of the Commissioned Drug Manufacture and Testing Operating Regulations.

Article 15 For application for registration and market approval for domestically-manufactured level 2 or level 3 medical device, the following documents shall be attached:

1. One copy each of the original and copy of the medical device registration and market approval application form.
2. Three copies each affixed or stapled to the label attachment form of the Chinese instructions, manual, packaging, and labels.
3. Photocopy of the permit license of the manufacturer of the medical device affixed or stapled to the license attachment form.
4. Affidavit (A).
5. Two copies each of pre-clinical trial and testing and original manufacturer quality control test specifications and methods, original test records, and test results report.
6. Two copies each of relevant documents concerning product structure, materials, specifications, functions, uses, and drawings, etc. However, in the case of instruments, operating manuals and service handbooks covering the items in this Subparagraph may be submitted instead.
7. Documents verifying that the domestic manufacturing plant complies with current good manufacturing practice for medical devices.
8. Theoretical basis and relevant research reports and data.
9. Clinical trial reports.
10. Two copies of radiation safety information for equipment generating ionizing radiation.

For documents mentioned in Subparagraph 7 of the foregoing Paragraph, if the medical device applying for registration and market approval is subject to management as a drug, photocopies of documents verifying compliance with current good manufacturing practice for drugs may be submitted instead.

The central competent health authority shall determine or announce whether the medical device applying for registration and market approval requires clinical trials in Taiwan in light of the medical device product item, the case,

and the materials submitted.

If the central competent health authority has already approved for sale a product similar to the medical device applying for registration and market approval, except where other regulations apply, the documents specified in Subparagraphs 8 and 9 of Paragraph 1 may be waived. However, the applicant shall additionally attach a domestic clinical trial report when clinical trials in Taiwan are required in accordance with the foregoing Paragraph.

Documents verifying approval of sale from the relevant authorities or agencies in the US and European Union member countries may be submitted instead of the documents in Subparagraph 5 of Paragraph 1 when the medical device applying for registration and market approval is of level 2. When necessary, however, other relevant documents shall be submitted in accordance with the central competent health authority's requests.

Documents in Subparagraphs 5, 6, 8, 9, and 10 of Paragraph 1 may be waived when the medical device applying for registration and market approval is exclusively for export.

With regard to the registration and market approval of in vitro diagnostic devices, except where the regulations of the foregoing six paragraphs apply, in which case the registration shall be handled in accordance with the central competent health authority's announcements, level 3 in vitro diagnostic devices shall be governed by the Regulations Governing Management of Medical Devices and requiring testing announced by the central competent health authority; such devices shall be submitted for testing in accordance with regulations.

When manufacturing or testing of a medical device applying for registration and market approval is commissioned, the application shall be handled in accordance with the foregoing seven paragraphs, and the manufacturing or testing so commissioned shall comply with the Commissioned Drug Manufacture and Testing Operating Regulations.

Medical devices applying for registration and market approval in accordance with regulations of Paragraphs 1, 5, and 6 shall also comply with relevant regulations announced by the central competent health authority.

Article 16 The following documents shall be attached when applying for registration and market approval of an imported level 1 medical device:

1. Original copy of a level 1 medical device registration and market approval application and affidavit.
2. Photocopy of permit license of medical device dealer affixed or stapled to the license attachment form.

When manufacturing or testing of a medical device applying for registration and market approval is commissioned, the manufacturing or testing shall comply with the Commissioned Drug Manufacture and Testing Operating Regulations.

Article 17 The following documents shall be attached when applying for the registration and market approval of an imported level 2 or level 3 medical device:

1. Original and one copy of the medical device registration and market approval application form.
2. Three copies each affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, and labels.
3. Photocopy of permit license of medical device dealers affixed or stapled to the license attachment form.
4. Affidavit (A).
5. Original copies of manufacturing and sales approval documents from country of origin.
6. Original copy of the foreign original manufacturer's authorization certificate.
7. Two copies each of pre-clinical trial and testing and original manufacturer quality control test specifications and methods, original test records, and test results report.
8. Two copies each of relevant materials concerning product structure, materials, specifications, functions, uses, and drawings, etc. However, in the case of instruments, operating manuals and service handbooks covering the items in this Subparagraph may be submitted instead.
9. Documents verifying that the plant manufacturing the imported medical device comply with current good manufacturing practice for medical devices.
10. Theoretical basis and relevant research reports and data.
11. Clinical trial reports.
12. Two copies of radiation safety information for equipment generating ionizing radiation.

If the medical device applying for registration and market approval is subject to management as a drug, the applicant may provide photocopies of documents verifying compliance with current good manufacturing practice for drugs instead of the documents in Subparagraph 9 of the foregoing Paragraph.

The central competent health authority shall determine or announce whether

the medical device applying for registration and market approval requires clinical trials in Taiwan in light of the medical device product item, the case, and the documents submitted.

If the central competent health authority has already approved for sale a product similar to the medical device applying for registration and market approval, except where other regulations apply, the documents specified in Subparagraphs 10 and 11 of Paragraph 1 may be waived. However, the applicant shall additionally attach a domestic clinical trial report when clinical trials in Taiwan are required in accordance with the foregoing Paragraph.

Documents verifying approval of sale from the relevant authorities or agencies in the US and European Union member countries may be submitted instead of the documents in Subparagraph 7 of Paragraph 1 when the medical device applying for registration and market approval if of level 2. When necessary, however, other relevant documents shall be submitted in accordance with the central competent health authority's requests.

When the medical device applying for registration and market approval is of level 2, the applicant may attach proof of manufacturing approval from the highest health agency in the country of manufacture and documents verifying approval of sale from the highest health agencies in the US or European Union member countries instead of the documents in Subparagraph 5 of Paragraph 1.

With regard to the registration and market approval of in vitro diagnostic devices, except where the regulations of the foregoing six paragraphs apply, in which case the registration shall be handled in accordance with the central competent health authority's announcements, in vitro diagnostic devices classified as level 3 in vitro diagnostic devices requiring testing pursuant to the Regulations Governing Management of Medical Devices and requiring testing announced by the central competent health authority; such devices shall be submitted for testing in accordance with regulations.

When manufacturing or testing is commissioned for medical devices applying for registration and market approval, the application shall be handled in accordance with regulations of the foregoing seven paragraphs, and the manufacturing or testing shall comply with the Commissioned Drug Manufacture and Testing Operating Regulations.

Medical devices applying for registration and market approval in accordance with regulations of Paragraphs 1, 5, and 6 shall also comply with relevant regulations announced by the central competent health authority.

Article 18 The following documents shall be attached when applying for registration and market approval of the same domestically-manufactured product under a

different name:

1. Original and one copy of the medical device registration and market approval application form.
2. Three copies each affixed or stapled to the label attachment form of Chinese instructions, manual, packaging, and labels.
3. Affidavit (A).
4. An explanatory letter from the original manufacturer explaining that the product for which a new application has been made and the originally-approved product are identical, and noting the permit number of the originally-approved medical device permit.
5. Photocopy of the originally-approved instruction label version bearing the central competent health authority's margin-overlapping seal.
6. Photocopy of the originally-approved medical device permit.
7. If the product name also bears the name or trademark of another manufacturer, the applicant shall attach a letter of consent from the company whose name or trademark has been added.

Article 19 The following documents shall be attached when applying for registration and market approval of the same imported product under a different name:

1. Original and one copy of the medical device registration and market approval application form.
2. Three copies each affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, and labels.
3. Affidavit (A).
4. Original copies of manufacturing and sales approval documents from country of origin, which shall explicitly state that the product for which a new application has been made and the originally-approved product are identical.
5. Original copy of the foreign original manufacturer's authorization certificate.
6. An explanatory letter from the original manufacturer explaining that the product for which a new application has been made and the originally-approved product are identical, and noting the permit number of the originally-approved medical device permit.
7. Photocopy of the originally-approved instruction label version bearing the central competent health authority's margin-overlapping seal.

8. Photocopy of the originally-approved medical device permit.
9. If the product name also bears the name or trademark of another manufacturer, the applicant shall attach a letter of consent from the company whose name or trademark has been added.

Chapter 3 Change, Transfer, and Re-issuance of Permit License

Article 20 After an application is reviewed and approved, apart from situations in which a permit license is damaged or lost and must be changed or reissued, in the event of changes, the central competent health authority shall note the registration changes and date on the original permit license, affix its seal, and return the permit license. A certificate fee must be paid, however, when new permit license is issued.

Article 21 The following documents shall be attached when applying for change of the Chinese product name on a medical device permit:

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Relevant documents shall be attached if a trademark is being registered.

Article 22 The following documents shall be attached when applying for change of the English product name on a medical device permit:

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Original copy of letter of explanation from the original manufacturer concerning the name change.
4. Original copies of manufacturing and sales approval documents from country of origin.
5. Relevant documents shall be attached if a trademark is being registered.

The documents in Subparagraph 4 of the foregoing Paragraph may be waived when applying to change the English product name on a domestically-manufactured medical device permit.

Article 23 The following documents shall be attached when applying for change of the original manufacturer's instructions, label, or packaging on a medical device permit:

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Original of the originally-approved instruction label version bearing the central competent health authority's margin-overlapping seal.

4. Original copy of a letter of explanation from the original manufacturer concerning the changes to instructions, label, or packaging.
5. Two copies each affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, and labels.

Article 24 The following documents shall be attached when applying to add specifications on a medical device permit:

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Original of the originally-approved instruction label version bearing the central competent health authority's margin-overlapping seal.
4. Two copies each affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, and labels.
5. Two copies each of pre-clinical trial and testing and original manufacturer quality control test specifications and methods, original test records, and test results report.
6. Two copies each of relevant documents concerning product structure, materials, specifications, functions, uses, and drawings, etc. However, in the case of instruments, operating manuals and service handbooks covering the items in this Subparagraph may be submitted instead.
7. Original copies of manufacturing and sales approval documents from country of origin.
8. Original copy of the foreign original manufacturer's authorization certificate.
9. Two copies of radiation safety information for equipment generating ionizing radiation.

The documents in Subparagraphs 7 and 8 of the foregoing Paragraph may be waived when applying to change a domestically-manufactured medical device permit.

Documents verifying approval of sale from the relevant authorities or agencies in the US or European Union member countries may be submitted instead of the documents in Subparagraph 5 of Paragraph 1 when applying to add specifications to a medical device of level 2. When necessary, however, other relevant documents shall be submitted in accordance with the central competent health authority's requests.

When the medical device for which an application to add specifications has

been made is a level 3 in vitro diagnostic reagent, apart from handling the case in accordance with the regulations in the foregoing four paragraphs, the applicant shall attach a letter of explanation from the original manufacturer, send the diagnostic reagent for testing in accordance with regulations, and, when necessary, attach stability test results and other relevant data.

Medical devices applying for registration change in accordance with regulations of Paragraphs 1 and 3 shall also comply with relevant regulations announced by the central competent health authority.

Article 25 The following documents shall be attached when applying to cancel specifications on a medical device permit:

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Original of the originally-approved instruction label version bearing the central competent health authority's margin-overlapping seal.

Article 26 The following documents shall be attached when applying to add efficacies on a medical device permit:

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Photocopy of the originally-approved instruction label version bearing the central competent health authority's margin-overlapping seal.
4. Two copies each affixed or stapled to the label attachment form of instructions and manual with detailed Chinese translations, packaging, and labels.
5. Two copies each of pre-clinical trial and testing and original manufacturer quality control test specifications and methods, original test records, and test results report.
6. Two copies each of relevant documents concerning product structure, materials, specifications, functions, uses, and drawings, etc. However, in the case of instruments, operating manuals and service handbooks covering the items in this Subparagraph may be submitted instead.
7. Original copies of manufacturing and sales approval documents from country of origin.
8. Original copy of the foreign original manufacturer's authorization certificate.
9. Academic theoretical basis and relevant research reports and data.
10. Clinical trial reports.

The documents in Subparagraphs 7 and 8 of the foregoing Paragraph may be waived when applying to change a domestically-manufactured medical device permit.

The documents in Subparagraphs 9 and 10 of Paragraph 1 may be waived when applying to add efficacies on a medical device permit for which a similar product has been approved for sale by the central competent health authority.

Documents verifying approval of sale from the relevant authorities or agencies in the US or European Union member countries may be submitted instead of the documents in Subparagraph 5 of Paragraph 1 when applying to add efficacies to a medical device of level 2. When necessary, however, other relevant documents shall be submitted in accordance with the central competent health authority's requests.

Medical devices applying for registration change in accordance with regulations of Paragraphs 1 and 4 shall also comply with relevant regulations announced by the central competent health authority.

Article 27 The following documents shall be attached when applying to change the manufacturing plant name on a medical device permit:

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Original copy of a letter of explanation from the original manufacturer concerning the change of plant name.
4. A photocopy of the permit license of the pharmaceutical company with the new plant name.
5. Original copies of manufacturing and sales approval documents from country of origin.
6. Original copy of the foreign original manufacturer's authorization certificate.
7. Photocopies of documents verifying that the manufacturing plant complies with current good manufacturing practice for medical devices.

The documents in Subparagraph 4 of the foregoing Paragraph may be waived when applying to change an imported medical device permit.

The documents in Subparagraphs 5 and 6 of the foregoing Paragraph may be waived when applying to change a domestically-manufactured medical device permit.

If the manufacturing plant for which the name change application is made is a commissioned manufacturer, apart from handling the application in accordance with regulations of the foregoing two paragraphs, shall comply with the

Commissioned Drug Manufacture and Testing Operating Regulations.

Article 28 The following documents shall be attached when applying to change the manufacturing plant site on a medical device permit (including change of country of manufacture):

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Original copy of a letter of explanation from the original manufacturer concerning change of the plant site.
4. A photocopy of the permit license of the pharmaceutical company with the new plant site.
5. Original copies of manufacturing and sales approval documents from country of origin.
6. Original copy of the foreign original manufacturer's authorization certificate.
7. Photocopies of documents verifying that the manufacturing plant complies with current good manufacturing practice for medical devices.

The documents in Subparagraph 4 of the foregoing Paragraph may be waived when applying to change an imported medical device permit.

The documents in Subparagraphs 5 and 6 of the foregoing Paragraph may be waived when applying to change a domestically-manufactured medical device permit.

The documents in Subparagraph 5 of Paragraph 1 may be waived when a change in manufacturing plant address occurs due to the reorganization of doorplates, but verifying documents from a government agency shall be attached.

When a change application is made for a level 3 in vitro diagnostic reagent, apart from handling the application in accordance with regulations of the foregoing four paragraphs, the applicant shall attach two copies each of pre-clinical trial and testing specifications and methods, original testing records, and testing result reports, and shall send the reagent for testing in accordance with regulations.

Article 29 The following documents shall be attached when applying for the rights transfer registration of medical device permit agency:

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Original copy of a permit letter of assignment from the drug company

transferring agency rights (assignor).

4. An affidavit from the drug company receiving agency rights (assignee) affirming responsible for the transferred drug.

5. Original copy of the foreign original manufacturer's authorization certificate; the content shall thoroughly relate that the assignor's registration rights are to be terminated and that the assignee shall perform registration, and shall state the product name and the names and addresses of assignor and assignee. If the medical device in question is imported, the foreign original manufacturer's authorization certificate shall also be notarized by an overseas representative organization of Taiwan, and shall have a validity period of one year from the date issued by the original manufacturer.

6. Affidavit (A).

Both assignor and assignee shall jointly apply for the registration in the foregoing Paragraph.

Article 30 An application for transfer registration shall be made in accordance with regulations of Article 29 when a change in the name of a drug company holding a medical device permit involves the transfer of rights.

The following documents shall be attached when applying for a change in the name of a pharmaceutical company holding a medical device permit when the transfer of rights is not involved:

1. Drug registration alteration application form.
2. Original copy of original permit license.
3. Photocopy of the drug company's permit license after name change.
4. One affidavit from the drug company after name change affirming responsible for each drug on the changed permit.

Article 31 The following documents shall be attached when applying for re-issuance of a lost or damaged medical device permit:

1. Drug registration alteration application form.
2. The original copy of the original permit license must be attached when applying for re-issuance of a damaged permit.
3. When lost, an affidavit stating that the original permit license is indeed lost must be attached.
4. Original and one copy of the medical device registration application form.

Article 32 When the medical device for which a change application is made belongs to level 1, apart from the regulations of this Chapter, the regulations of Articles 14 and 16 shall also apply.

Article 33 When the medical device for which a change application is made is exclusively for export, apart from the regulations of this Chapter, the application materials shall be simplified in accordance with regulations of Article 15.

Chapter 4 Extension of a Permit License

Article 34 Application for extension of the validity period of a medical device permit license shall be made within three months of the expiration. Those who fail to apply for an extension before the deadline must re-apply for registration, and may not submit extension applications.

However, those who re-apply for registration within six months after the expiration of the validity period of their original permit license may attach a registration application form in accordance with regulations of Article 35, and enjoy simplified application procedures.

Article 35 The following documents shall be attached when applying for extension of the validity period of a medical device permit license:

1. A medical device import (manufacture) permit license validity period extension application form approved by the special municipality, county and city competent health authority of the pharmaceutical company's locality.
2. Original copy of original permit license.
3. Original copies of manufacturing and sales approval documents from country of origin.
4. Original copy of the foreign original manufacturer's continued authorization certificate.
5. Documents verifying that the manufacturing plant complies with current good manufacturing practice for medical devices. These documents may be waived, however, when, in accordance with the Regulations Governing Management of Medical Devices, the product item does not require current good manufacturing practice for medical devices.

The documents in Subparagraphs 3 and 4 of the foregoing Paragraph may be waived when applying for an extension for a domestically-manufactured medical device permit license.

The documents in Subparagraph 3 of Paragraph 1 may be waived when applying for an extension for a level 1 medical device permit license.

If the medical device for which a permit license extension has been made is subject to management as a drug, the applicant may provide photocopies of documents verifying compliance with current good manufacturing practice for

drugs instead of the documents in Subparagraph 5 of Paragraph 1.

A manufacturing plant that has received a medical device permit license but fails to comply with current good manufacturing practice for medical devices shall not be granted a permit license extension. This restriction shall not apply, however, when the situation in Subparagraph 5 of Paragraph 1 is present.

Chapter 5 Supplementary Provisions

Article 36 With regard to the drafting and publication of medical device instructions, labels, and packaging, apart from complying with regulations of Article 75 of this Act and regulations announced by the central competent health authority, the applicant must also change, revise, or supplement relevant materials as requested by the central competent health authority.

The instructions, labels, and packaging of domestically-manufactured medical devices shall be primarily in Chinese. Any included foreign characters must be smaller than Chinese characters. Apart from the required inclusion of Chinese instructions, the labels and packaging of imported medical devices shall include the product name, permit number, and name and address of the importing drug company in Chinese. In addition, the date of manufacture and validity period or storage life shall be expressed in Chinese or using some other readily distinguishable method. The characters of the Chinese product may not be smaller than those of the foreign product name.

Article 37 The product name of a medical device shall comply with the following regulations:

1. A product name may not use a third party drug trademark or manufacturer name. The applicant shall not be subject to this restriction, however, if it has acquired the trademark or been authorized to use the trademark.
2. A product name may not have the same name as that of a medical device made by another manufacturer, and may not rely on imitation or insinuation.
3. A product name may not contain falsehoods, exaggerations, or anything that causes people to give rise to incorrect associations or confusion concerning the medical device and its effectiveness.
4. A Chinese product name may not contain foreign characters or numerals. Those names directly conveying certain meaning shall not be subject to this restriction, however.
5. A product name may not have other circumstances not appropriate for the name of a medical device.

The precedence of medical device names that are identical or similar shall be

determined on the basis of the precedence of trademarks, company names, or other identifiable names.

The central competent health authority may review the name of a medical device already approved for sale in accordance with regulations of the two foregoing paragraphs.

Article 38 These Guidelines shall come into force from the date of announcement.