Provisions on Registration and Administration of Medical Devices

Order No.16 of the State Food & Drug Administration

This *Provisions on Registration and Administration of Medical Devices* is discussed and approved by the meeting of State Food & Drug Administration on May 28, 2004 and is hereby promulgated officially. It shall take effect as of the date on which it is published.

Zheng Xiaoyu
Director
State Food & Drug Administration
August 9, 2004

Provisions on Registration and Administration of Medical Devices

Chapter I General Provisions

Article 1 The Provisions on Registration and Administration of Medical Device (hereinafter referred to as "the Provisions") is hereby enacted in accordance with *Regulations on Supervision and Administration of Medical Devices*, and with a view to standardize the registration of medical devices (hereinafter referred to as "MD") and to guarantee the safety and effectiveness of MD.

Article 2 All the MD to be sold and used in China shall be applied for registration in accordance with the Provisions. The MD without such registration may not be sold and applied in China.

Article 3 MD registration refers to the process in which a systemic assessment is carried out, according to the legal procedures, on the safety and effectiveness of the MD to be sold and used.

Article 4 The state implements MD registration by way of classification.

The domestic MD under Class I shall be examined by the (food &) drug administrations affiliated to governments of municipalities consisting of districts. A Registration Certificate of MD is to be issued to qualified applicant upon approval.

The domestic MD under class II shall be examined by the (food &) drug administration affiliated to governments of provincial level. A Registration Certificate of MD is to be issued to qualified applicant upon approval.

The domestic MD under class III shall be examined by the State Food & Drug Administration (hereinafter referred to as "SFDA"). A Registration Certificate of MD is to be issued to qualified applicant upon approval.

The overseas MD shall be examined by the SFDA. A Registration Certificate of MD is to be issued to qualified applicant upon approval.

The MD produced in Taiwan, Hong Kong and Macao applied to be sold and used in Chinese mainland shall be examined by the SFDA, except otherwise provided for in the Provisions.

The term of validity for the registration certificate of MD is four years.

Article 5 The Registration Certificate of MD shall be printed by the SFDA with a uniform standard. The contents of such certificate shall be filled out by the (food &) drug regulatory authorities who have examined and approved the registration.

The registration numbers are arranged as follows:

X (X)1 (Shi)Yaojianxie (X2) Zi XXXX3 No. X4 XX5 XXXX6.

Among which:

X1 refers to the abbreviation for the location of registration authority:

For domestic MD under Class III, overseas MD and MD produced in Taiwan, Hong

Kong and Macao, it shall be “Guo”.

For domestic MD under Class II, it shall be the abbreviation for the provinces, autonomous regions and municipalities directly under the central government where the registration authority is located.

For domestic MD under Class I, it shall be the abbreviation for the provinces, autonomous regions and municipalities directly under the central government + the abbreviation for the municipality consisting of regions, where the registration authority is located, in a form of XX1. (If the municipality doesn’t consist of districts, it shall just be the abbreviation for the provinces, autonomous regions and municipalities directly under the central government).

X2 refers to the mode of registration (zhun, jin or xu);

“zhun” applies to domestic MD;

“jin” applies to overseas MD;

“xu” applies to MD produced in Taiwan, Hong Kong and Macao.

XXXX3 refers to the year of registration;

X4 refers to the administration type of MD;

XX5 refers to the type code of MD;

XXXX6 refers to the registration serial number.

An MD Registration Form (see *Appendix 1*) attached to the Registration Certificate is to be used together with the certificate.

Article 6 The manufacturer shall file the application for MD registration, and bear the corresponding legal liabilities. And it will hold the ownership of such certificate.

The person who engages in the application for MD registration shall be entrusted by the MD manufacturer, and have the related professional knowledge, and be familiar with the laws, regulations, provisions and technical requirements governing the MD registration.

For the application for overseas MD registration, the overseas manufacturer shall designate an institution within the territory of China as its agent. And such agent shall assume the related legal responsibilities. In addition, the overseas manufacturer shall entrust a qualified legal entity within China or its office in China as its service agent.

Article 7 The MD applied for registration shall meet the applicable product standards—may employ national standards, industrial standard or draw up the standards for such MD, which, however, shall be not below the national standards or industrial standards.

The standards for the MD applied for registration shall be drawn up in accordance with the management requirements for MD standards set up by SFDA.

Article 8 For the application for registration of MD under Class II and III, the manufacturer shall meet the requirements for manufacturing facilities stipulated by SFDA or related quality system requirements.

Chapter II MD Registration Test

Article 9 When applied for registration, the MD under Class II and III shall be tested by a MD testing institution certified by SFDA and AQSIQ. Only the MD that has passed the test on standards may be applied in clinical trials or for registration.

The catalogue for the MD testing institutions approved by SFDA and AQSIQ will be issued separately.

Article 10 The MD testing institutions shall conduct the registration test, within the test scope certified by SFDA and AQSIQ, on the declared MD and issue test report in accordance with the standards declared applicable for the MD (including the applicable national standards, industrial stands or the standards for the product applied for registration drawn up by the manufacturer)

For the MD still not covered by the test scope certified by various MD testing institutions, the registration and approval authority shall designate a qualified testing unit to conduct the registration test.

For the registration test on overseas MD, *Regulations on Registration Test on Overseas MD* shall be applicable.

Article 11 The tested product shall be typical of the complete registration unit in terms of safety and effectiveness.

Article 12 For the products under the same category made of the same raw materials by the same manufacturer, another biological compatibility test on biological evaluation may be skipped when applied for re-registration, if the production process and intended usage maintain unchanged.

In the event that the same manufacturer made the products under the same category out of the raw materials that have passed the biological evaluation, another biological compatibility test on biological evaluation may be skipped when applied for registration, if the production process and intended usage remain unchanged or no potential biological risk is added.

Article 13 When applied for registration of MD under Class II and III, the registration test may be exempt if all the following conditions are met:

1. The MD applied for registration and those registered MD produced by the same manufacturer fall into the same category in terms of basic principles, major functions, structure, materials, material quality and intended usage.

2. The manufacturer has passed the inspection on Quality Control Criteria of MD Production or has acquired a MD quality system certification, and the manufacturer is able to provide an inspection report on manufacturing facilities of original manufacturer issued by the original inspection authority.

3. When the MD applied for registration is compared with the products of the same category produced by the same manufacturer that has been registered and passed the registration test, no change involving safety and effectiveness has been found out, or, even if there are changes involving safety and effectiveness, the changed parts and those parts that have been changed consequently with respect of safety and effectiveness have passed the test conducted by an MD testing institution.

4. The registered products of the same category produced by the same manufacturer have been monitored with respect to the adverse-effect events in accordance with the relevant regulations, and no seriously adverse-effect events have been found.

5. The registered products of the same category produced by the same manufacturer have no record of substandard products within one (1) year during the spot check by (food &) drug administrations.

6. The overseas MD has been approved for sales by competent overseas authorities.

Article 14 When applied for re-registration of MD under Class II and III, the registration test may be exempt if all the following conditions are met:

1. The MD applied for registration and those registered MD produced by the same manufacturer fall into the same category in terms of basic principles, major functions, structure, materials, material quality and intended usage.

2. The manufacturer has passed the inspection on Quality Control Criteria of MD Production or has acquired a MD quality system certification, and the manufacturer is able to provide an inspection report on manufacturing facilities of original manufacturer issued by the original inspection authority.

3. When the MD applied for re-registration is compared with the products of the same category produced by the same enterprise that has been registered and passed the registration test, no change involving safety and effectiveness has been found out, or, even if there are changes involving safety and effectiveness, the changed parts and those parts that have been changed consequently with respect of safety and effectiveness have passed the test conducted by an MD testing institution.

4. The MD applied for re-registration have been monitored with respect to the adverse-effect events in accordance with the relevant regulations, and no seriously adverse-effect events have been found within the term validity of original Registration Certificate of MD.

5. The formerly registered MD has no record of substandard products within one (1) year during the spot check by (food &) drug administrations.

Article 15 For the large MD that has been approved for sales by the competent overseas authorities, and imposes special requirements on installation site, and are difficult to test, the manufacturer may apply for a delayed test. Upon acquiring the Registration Certificate of such MD, a supplementary test shall be conducted.

For the MD product that has bee applied for a delayed test and has gained registration in accordance with the aforesaid provision, the manufacturer must complete the registration test after the first MD enters into China and before putting into service. Only the MD that has passed the test is allowed to be put into use.

Chapter III Clinical Trials of MD

Article 16 When applying for the registration of MD under Class II and III, the applicant shall submit the materials of clinical trials.

The materials of clinical trials shall be provided in accordance with *Provisions on Report Items of Clinical Trials for MD Registration* (See *Appendix 12*).

Article 17 The clinical trials of MD conducted within the territory of PRC shall strictly comply with *Provisions of Clinical Trials of MD.*

Article 18 For the MD whose clinical trials have been conducted within the territory of PRC, the materials of clinical trials shall include contract of clinical trials, plan of clinical trials and report of clinical trials.

The manufacturer may be required to submit notice to clinical trials, letter of consent and original record of clinical trials, if the (food &) drug administration considers such materials necessary.

Chapter IV Application and Approval of MD Registration

Article 19 When applying for an MD registration, the applicant shall fill an application to the competent (food &) drug administration as provided for in Article 4 of the Provisions, based on the classification of MD. The applicant shall also fill out the *Application for MD Registration*, and submit the application materials in accordance with Appendix 2, 3,6,8 or 9. A Chinese version of the application materials shall be submitted. If the application materials are translated from foreign languages, the original version shall be submitted.

The instruction manual of MD that the applicant submits shall comply with the *Management Provisions on Instruction Manual, Labeling and Packaging*.

The applicant shall be responsible for the authenticity of the full contents of the application materials.

Article 20 Upon receiving the application for registration, (food &) drug Administration, based on different circumstances, shall:

1. make a decision of rejection and notify the applicant to file the application to a competent administrative organ, if the items being applied for are beyond its scope of authority.

2. allow the applicant immediately correct the errors in the application materials, if appropriate.

3. give the applicant a *Notice to Supplement or Correct Materials* immediately or within 5 working days and notify , once for all, the applicant what to be supplemented or corrected, if the application materials are not complete or not meet the requirements of elementary inspection. The date on which the application materials are received will be considered as the acceptance date, if no notification is given within the aforesaid period.

4. accept the application if the application materials are complete and meet the requirements of elementary inspection, or the applicant submits all the materials

that has been asked to supplement or correct .

(Food &) Drug administration shall issue either a *Notice of Acceptance* or a *Notice of Rejection* with its specialized seal and date.

Article 21 Upon accepting the application for MD registration, the (Food &) Drug Administration shall conduct a substantial inspection on the application and make a written decision whether to approve the application for registration within the period stipulated in Article 22 of the Provisions. If the application passed the inspection, a Registration Certificate of MD shall be issued within 10 working days after the written decision of approval was made. If the application didn't pass the inspection, a written decision of rejection shall be issued, accompanied by written explanations. And the applicant shall be informed of the right to apply for administrative review or file administrative suit in people's court.

Article 22 The (food &) drug administration affiliated to the governments of municipalities consisting of regions shall determine where to approve the application for registration within 30 working days after accepting such application.

The (food &) drug administration affiliated to provincial governments shall determine where to approve the application for registration within 60 working days after accepting such application.

SFDA shall determine where to approve the application for registration within 90 working days after accepting such application.

During the inspection period, if a test, experts' review, or public hearing is required, the time spent on such issues will be excluded from the counting down of the said time limit of inspection. The (food &) drug administration shall notify the applicant the necessary time on such issues in a written form.

Article 23 When the overseas MD that has not acquired an approval of sales is applied for registration, the technical inspection requirements for registration of domestic products of the same category shall be referred to. (See *Appendix 8* and *Appendix 9* for the materials required to be submitted).

Article 24 When the (food &) drug administration conducts the technical inspection on the application materials for MD registration, if requiring the manufacturer to submit supplementary materials, it shall, once for all, give a written notice to supplement materials.

The manufacturer shall submit the supplementary materials once for all in accordance with such notice within 60 working days. The time spent on waiting for such supplementary materials will be excluded from the counting down of the said time limit of substantial inspection. If the manufacturer fails to submit the supplementary materials within the stipulated period and has no justified reasons, the substantial inspection shall be terminated.

Article 25 In the event that the inspection on application for registration is terminated, the applicant shall not apply for application of registration once again within 6 moths after termination of inspection.

Article 26 In the event that any manufacturer is dissatisfied with the notice to supplement materials, the manufacturer may submit a written report of opinions to the (food &)

drug administration within the stipulated time limit. Reasons for dissatisfaction shall be included in such report, and the technical supporting materials shall be provided. The (food &) drug administration shall make a decision after conducting an examination on such report and materials.

Article 27 The registration categories of MD products shall be determined in accordance with different technical structures, performance index and intended usage.

Article 28 For MD registered in part(s), the applicant shall also recommend supporting products or part (s) to be used together with the registered part(s) and provide their names, specifications and models.

For any complete unit composed of parts that all have been registered, the applicant shall apply for registration of such complete unit separately.

For product registered in complete unit, the applicant shall make a list of key supporting parts. If there is any change to the performance index of a certain part, the applicant shall apply for re-registration.

For product that has been registered in complete unit, if the composing parts listed in the column of “Performance, Structure and Components of the Product” have not been modified with respect to composing form and intended usage, the composing parts can be sold with an exemption from separate registration.

Article 29 The (food &) drug administrations shall publish the required conditions, procedures, time limit, catalog of application materials, model of application file, etc. on the websites of the administrative organs or on the bulletin board of the place of business of registration authorities.

Article 30 The (food &) drug administrations shall publish the process and results of examination and approval when inspecting the application for MD registration. The applicant and/or person of interest may submit a written report of opinions to state or defend with respect to the issues that directly relate to their major interests and benefits.

Article 31 SFDA shall periodically publish the catalog of MD that have been approved of registration on its government website, for public reference.

Article 32 In the event that the application for MD registration directly involves the major interests and benefits between the applicant and others, the (food &) drug administrations shall inform the applicant and the person(s) of interest of the right to apply for a public hearing. When the (food &) drug administrations conducts the inspection on the application for MD registration, if a major license item is considered to involve public interests, it shall be announced to the public and a public hearing shall be held.

Chapter V Re-registration of MD

Article 33 In the event that the manufacturer wants to continue selling or using the MD after the expiration of the Registration Certificate, it shall apply for re- registration within six (6) months prior to the expiration of such certificate. If an application for re-registration is filed beyond such time limit, a registration test shall be conducted.

Article 34 In the event that the following contents in the Registration Certificate of MD are modified, the manufacturer shall apply for a re-registration of modification within 30 days after the modification occurs.

1. Model, specifications
2. Address of manufacturing site
3. Product standards
4. Performance, structure and components of product
5. Indications

Article 35 Within the term of validity of Registration of Certificate, if the regulatory classification changed, the manufacturer shall apply for re-registration of the MD under the changed category to the competent (food &) drug administration within 6 months.

Article 36 For application for re-registration of MD, the applicant shall fill out a *Application for MD Registration*, and submit the required application materials to the competent (food &) drug administration in accordance with *Appendix 4, 5 or 7* of the Provisions.

For the procedurals of acceptance and inspection for re-registration not provided for in this Chapter, the stipulations set up in Chapter IV of the Provisions shall be applicable.

Article 37 Re-registration shall not be approved if the MD applied for registration falls under the following categories:

1. not completing the requirements put forward by the registration authority when it approved such MD for sales, according to the relevant provisions issued by SFDA.
2. belonging to obsolescent type upon re-assessment by SFDA
3. revoked the Registration Certificate of MD according to *Provisions on Supervision and Administration of MD.*

Chapter VI Modification and Re-application for Registration Certificate of MD

Article 38 In the event that the manufacturer changes one of the following contents listed in Registration Certificate of MD, the manufacturer shall apply for modification of Registration Certificate within 30 days after such change.

1. Changing the name of the Manufacturer while keeping the enterprise entity unchanged.
2. Changing the Manufacturer's Address
3. Changing the wording of Address of Manufacturing Site
4. Changing the wording of Name of Device
5. Changing the wording the Model and Specifications
6. Changing the Agent

7. Changing the Service Agent(s)

Article 39 In the event the manufacturer applies for modification of Registration Certificate of MD, the applicant shall fill out the *Application for Modification of Registration Certificate of MD*, and shall submit the required materials and a statement of explanations to the original registration authority in accordance with *Appendix 10* attached to the Provisions. After conducting an elementary inspection on the submitted materials, the original registration authority shall, immediately or within 5 working days, notify, once for all, the applicant what to supplement or correct, or issue an *Notice of Acceptance* to the applicant if such materials meet the relevant requirements.

Article 40 Upon acceptance of the application for modification, the original registration authority shall make a written decision whether to approve the application for modification within 20 working days. In the event the application for modification has passed the inspection, a renewed certificate shall be issued and the original certificate shall be cancelled. In the event that the application has not passed the inspection, the registration authority shall make a written decision of rejection, accompanied with explanations, and shall notify the applicant that he/she is entitled to file an application for administrative review or file an administrative suit in the people's court.

For modification of the Registration Certificate, the original serial number is still valid and a "(Geng)" (meaning "modified") will be added to end of the original serial number.

The term of validity of the renewed certificate shall be equivalent to the remaining term of the original certificate. Upon expiration of the term of validity, the manufacturer shall file an application of re-registration.

Article 41 In the event that the Registration Certificate is lost or damaged, the manufacturer shall re-apply for the same Registration Certificate by submitting the required materials and a statement to the original registration authority.

Chapter VII Supervision and Administration

Article 42 The (food &) drug administrations shall conduct the examination and approval of MD registration in accordance with the relevant provisions, and shall make a decision whether to approve the application for registration. In the event, such authority breaches the relevant provisions when examining and approving the application for registration, it will be investigated for administrative liabilities.

Article 43 In the event that the local (food &) drug administrations affiliated to the governments above municipal level wrongly grant Registration Certificate and breach the Provisions, the (food &) drug administrations of above level shall order them to correct their mistakes within the specified period. If such administrations fail to correct their mistakes within the specified period, the (food &) drug administrations of above level can make a public announcement to revoke the unlawful Registration Certificate of MD. The MD with the revoked certificate shall not be sold or applied. For those which have been sold or applied, the local (food &) drug administrations affiliated to the governments above county level shall supervise the enterprises to

deal with.

Article 44 The (food &) drug administrations affiliated to the governments above provincial level shall conduct the technical re-evaluation on the MD approved for sales, and shall make a public announcement to revoke the Registration Certificate in the event that the results of such technical re-evaluation show that the MD can not meet the intended usage or not ensure the safety and effectiveness. The MD with the revoked certificate shall not be sold or applied. For those which have been sold or applied, the local (food &) drug administrations affiliated to the governments above county level shall supervise the enterprises to deal with.

Article 45 Any Registration Certificate of MD falling under any of the categories of Article 70 in the *Law of Administrative Licensing of People's Republic of China* shall be revoked by the original registration authority.

Chapter VIII Legal Responsibility

Article 46 In the event that any enterprise or individual violates the Provisions and provides false certificates, documents and samples when applying for registration of MD, or attempt to obtain the Registration Certificate of MD by other unjust means of deceit or bribery, the registration authorities shall not accept or approve such application, and shall give a warning, and shall not accept any application for registration of MD from such enterprise or individual within 1 year. For those who have obtained the Registration Certificate of MD by aforesaid unlawful means, the registration authorities shall revoke the Registration Certificate of MD and shall not accept any application for registration from such enterprise or individual within two years. In addition, a fine shall be imposed in accordance with Article 40 in R*egulations on Supervision and Administration of MD.*

Article 47 In the event that any enterprise or individual erases, alters, falsifies, resells, or leases the Registration Certificate of MD, or unlawfully transfers such certificate by any other means, the (food &) drug administrations affiliated to governments of county level shall order them to rectify the situation. In addition, a fine below Rmb 30,000 may be imposed on them.

Article 48 In the event that any enterprise or individual violates the stipulations of Article 33, 34 or 35 in the Provisions to sell unregistered MD, or to sell the MD that is different from the contents of the Registration Certificate, or to sell the MD with instruction manual, labeling or packaging being different from the contents of the Registration Certificate, the (food &) drug administrations affiliated to governments of county level shall punish them in accordance with the stipulations governing MD without Registration Certificate in *Provisions on Supervision and Administration of MD.*

Article 49 In the event that any enterprise or individual violates the stipulations of Article 38 of the Provisions not to go through an modification of Registration Certificate of MD, the (food &) drug administrations affiliated to governments of county level shall order them to rectify the situation within specified period or give a warning. If such enterprise or individual fails to correct the situation within the specified period, a fine of Rmb 5000-10000 may be imposed on them.

Article 50 In the event that any MD that may be tested after being applied for registration,

according to Article 15 of the Provisions, is put into service without completing a registration test, SFDA shall make a public announcement to revoke the Registration Certificate and put such matter in the Records of Enterprise's Good Faith

If the MD is found out substandard during the registration test, SFDA shall revoke the Registration Certificate of such MD.

Chapter IX Supplementary Provisions

Article 51 Manufacturer refers to such organization that puts the products to the market under its own name and assumes the final legal liabilities.

Article 52 Registered Product refers to such MD that has obtained a Registration Certificate and its instruction manual, labeling and packaging marks being consistent with the contents of the Registration Certificate.

Article 53 Any MD produced within the term of validity of Registration Certificate will be considered as MD with registration.

Article 54 For the reagents for in vitro diagnosis governed by the administration of MD registration, the provisions on administration of registration of such reagents shall be provided for separately.

Article 55 The power of interpretation of the Provisions pertains to the State Food and Drug Administration.

Article 56 The Regulations shall go into effect on the day it is promulgated. The original *Provisions on the Administration of MD Registration* promulgated on April 5, 2000 by State Pharmaceutical Administration will become expired at the same time.

Appendix:

1. Format for MD Registration Form
2. Materials to be submitted when applying for registration of Domestic MD under Class I
3. Materials to be submitted when applying for registration of Domestic MD under *Class II and III*
4. Materials to be submitted when applying for re-registration of Domestic MD under Class I
5. Materials to be submitted when applying for re-registration of Domestic MD under *Class II and III*
6. Materials to be submitted when applying for registration of Overseas MD
7. Materials to be submitted when applying for re-registration of Overseas MD
8. Materials to be submitted when applying for initial registration of Overseas MD under Class I that has not acquired a sales permit for overseas MD.
9. Materials to be submitted when applying for initial registration of Overseas MD under Class II and III that has not acquired a sales permit.
10. Materials to be submitted when applying for modification of the MD Registration Certificate
11. Materials to be submitted when re-applying for MD Registration Certificate
12. *Provisions on Report Items of Clinical Trials for MD Registration*

Appendix 1

Format for MD Registration Form

1. Format for Domestic MD Registration Form:
MD Registration Form

REG. No.: ×(×)1 (*Shi*) Y*aoJianXie* (*Zhun*) *Zi* ××××3 No.×4××5××××6

Manufacturer	
Manufacturer's Address	
Address of Manufacturing Site	
Name of Device	
Model, specifications	
Product Standard	
Performance, Structure and Components of the Product	
Indications	
Contraindications	
Notes	**××××year×month×day**

2. Format for Overseas MD Registration Form:

MD Registration Form

REG. NO.: *GuoShiYaoJianXie (Jin) Zi*××××× No.x4××5××××6

Manufacturer	
Manufacturer's Address	
Address of Manufacturing Site	
Name of Device	
Model	
Product Standard	
Performance, Structure and Components of the Product	
Indications	
Contraindications	
Agent	
Service Agent (s)	
Notes	**××××year ×month ×day**

3. Format of Form for Registration of MD Produced in Taiwan, Hong Kong and Macao: MD Registration Form

REG. NO.: *GuoShiYaoJianXie* (X*u*) Z*i* ××××3 No.×4××5××××6

Manufacturer	
Manufacturer's Address	
Address of Manufacturing Site	
Name of Device	
Model	
Product Standard	
Performance, Structure and Components of the Product	
Indications	
Contraindications	
Agent	
Service Agent (s)	
Notes	**××××year ×month ×day**

Appendix 2

Materials to Be Submitted When Applying for Registration of Domestic MD under Class I

1. Application for Domestic MD Registration

2. Qualification certificate of MD manufacturer

   Duplicate of Business License

3. Applicable product standards and related explanations

   In the event that the national standards or industrial standards are employed, the applicant shall present the text of the employed national standards or industrial standards. In the event that the registered product standards are employed, the applicant shall submit the text of the employed registered product standards with the signature and/or seal of the manufacturer.

   The manufacturer shall provide a statement that states the product applied for registration complies with the employed national standards or industrial standards. In addition, the manufacturer shall provide a statement that states it will bear the quality liabilities after such product are approved for sales, and a statement of explanations on the classification of model and specifications of the products involved.

   “Signature and/or seal” hereof refers to the seal of the manufacturer, or the signature of the legal representative or person chief-in-charge plus the seal of the manufacturer. (for domestic MD, hereinafter with the same meaning).

4. A self-test report on performance of the product;

5. A description of the existing resources, conditions and capacity of quality management (including means of test) for the production;

6. Instruction manual of the product; and

7. A statement of guarantee on the authenticity of the materials submitted.

   The list of the submitted materials and a statement of commitment on assumption of legal responsibilities shall be included.

Appendix 3

Materials to Be Submitted When Applying for Registration of Domestic MD under Class II and III

1. Application for Domestic MD Registration

2. Qualification certificate of MD manufacturer

   Manufacturer's Permit and copies of Business license shall be included. In addition, the product(s) applied for registration shall fall within the certified scope of production on the Manufacturer's Permit.

3. A technical report of the product;

   At least the basis for determining the technical indexes or major performance requirements shall be included.

4. Analysis Report on risks and Safety

   It shall be compiled according to the requirements of YY0316 *Risk Analysis of MD*. Analysis of the following aspects of hazard and their relevant preventive measures shall be included in the report: energy hazard, biology hazard, environment hazard, operation related hazard, and hazard caused by malfunction, bad maintenance and aging.

5. Applicable product standards and related explanations

   In the event that the national standards or industrial standards are employed, the applicant shall present the text of the employed national standards industrial standards. In the event that the registered product standards is employed, the applicant shall submit the text of the employed registered product standards with the signature and/or seal of the manufacturer.

   The manufacturer shall provide a statement that states the product applied for registration complies with the employed national standards or industrial standards. In addition, the manufacturer shall provide a statement that states it will bear the quality liabilities after such product are approved for sales, and a statement of explanations on the classification of model and specifications of the products involved.

6. A self-test report on performance of the product;

   The items of self-test on performance of the product refers to the factory release test items provided for in the registered product standards. Such self-test report shall be accompanied with the signature of the chief inspector or inspection director and the verifier. In the event that the national standards or industrial standards are employed, the manufacturer shall supplement the self-defined factory release test items.

7. A test report on the MD applied for registration issued by MD testing institutions

   For the MD necessary for clinical trials, the applicant shall submit a test report issued by MD testing institutions within half a year prior to commencement of clinical trials. For the MD unnecessary for clinical trials, the applicant shall submit a test report issued by MD

testing institutions within one (1) year prior to the acceptance of registration.

In the event the provisions in Article 11, Article 12, Article 13 or Article 14 are applicable, the applicant shall present the related statement of explanations.

8. MD Clinical Trials Materials (refer to Appendix 12 for details)

9. Instruction Manual of the product; and

10. Valid certificates for quality system examination (certification) on production of product—An examination report on quality system shall be submitted dependent on the requirements for different products.

    (1) An examination report on quality system within the term of validity and attached by the seal of the (food &) drug administrations affiliated to the governments of provincial level.

    (2) A check report on quality management criteria of the production of MD or a certificate of quality system certification on MD.

    (3) In the event that the state has brought into effect the implementation details for MD production, an inspection report on compliance with such implementation details shall be presented.

11. A statement of guarantee on the authenticity of the materials submitted.

    The list of the submitted materials and a statement of commitment on assumption of legal responsibilities shall be included.

Appendix 4

Materials to Be Submitted When Applying for Re-registration of Domestic MD under Class I

1. Application for Domestic MD Registration

2. Qualification certificate of MD manufacturer

   Duplicate of business license.

3. Original registration certificate of MD

   In the event that the situations provided or in Article 33 in Chapter V of the Provisions exist, the copies of the original registration certificate of MD shall be submitted. In the event that the situations provided for in Article 34 or Article 35 in Chapter V of the Provisions exist, the original registration certificate of MD shall be submitted.

4. Applicable product standards and related explanations

   In the event that the national standards or industrial standards are employed, the applicant shall present the text of the employed national standards industrial standards. In the event that the registered product standards is employed, the applicant shall submit the text of the employed registered product standards with the signature and/or seal of the manufacturer.

   The manufacturer shall provide a statement that states the product applied for registration complies with the employed national standards or industrial standards. In addition, the manufacturer shall provide a statement that states it will bear the quality liabilities after such product are approved for sales, and a statement of explanations on the classification of model and specifications of the products involved.

5. Quality tracking report of product

6. Instruction Manual of MD

7. In the event that the situation provided for Article 34 in Chapter V of the Provisions exists, a statement of explanations and certifying documents shall be submitted.

8. A statement of guarantee on the authenticity of the materials submitted.

   The list of the submitted materials and a statement of commitment on assumption of legal responsibilities shall be included.

Appendix 5

Materials to Be Submitted When Applying for Re-registration of Domestic MD under Class II and III

1. Application for Domestic MD Registration

2. Qualification certificate of MD manufacturer

   Manufacturer's Permit and copies of Business license shall be included. In addition, the product(s) applied for registration shall fall within the certified scope of production on the Manufacturer's Permit.

3. Original registration certificate of MD

   In the event that the situations provided or in Article 33 in Chapter V of the Provisions exist, the copies of the original registration certificate of MD shall be submitted. In the event that the situations provided or in Article 34 or Article 35 in Chapter V of the Provisions exist, the original registration certificate of MD shall be submitted.

4. A test report on the MD applied for registration issued by MD testing institutions

   For the MD necessary for clinical trials, the applicant shall submit a test report issued by MD testing institutions within half a year prior to commencement of clinical trials. For the MD unnecessary for clinical trials, the applicant shall submit a test report issued by MD testing institutions within one (1) year prior to the acceptance of registration.

   In the event the provisions in Article 11, Article 12, Article 13 or Article 14 are applicable, the applicant shall present the related statement of explanations.

5. Applicable product standards and related explanations

   In the event that the national standards or industrial standards are employed, the applicant shall present the text of the employed national standards industrial standards. In the event that the registered product standards is employed, the applicant shall submit the text of the employed registered product standards with the signature and/or seal of the manufacturer.

   The manufacturer shall provide a statement that states the product applied for registration complies with the employed national standards or industrial standards. In addition, the manufacturer shall provide a statement that states it will bear the quality liabilities after such product are approved for sales, and a statement of explanations on the classification of model and specifications of the products involved.

6. Quality tracking report of product

   The applicant shall present a quality tracking report of product issued by the manufacturer after the application of such product in Chinese medical units, in which a statement of explanation on adverse-effect events monitoring shall be included.

7. Instruction Manual of MD;

8. Valid certificates for quality system examination (certification) on production of

product—An examination report on quality system shall be submitted dependent on the requirements for different products.

(1) An examination report on quality system within the term of validity and attached by the seal of the (food &) drug administrations affiliated to the governments of provincial level.

(2) A check report on quality management criteria of the production of MD or a certificate of quality system certification on MD.

(3) In the event that the state has brought into effect the implementation details for MD production, an inspection report on compliance with such implementation details shall be presented. ;

9. In the event that the situation provided for Article 34 in Chapter V of the Provisions exists, a statement of explanations and certifying documents shall be submitted.

10. A statement of guarantee on the authenticity of the materials submitted.

The list of the submitted materials and a statement of commitment on assumption of legal responsibilities shall be included.

Appendix 6

Materials to Be Submitted When Applying for Registration of Overseas MD

1. Application for Overseas MD Registration

2. Qualification certificate of MD manufacturer

3. Duplicate of business license of the applicant, and a letter of authorization on registration granted by the manufacturer

4. Certificate issued by overseas MD administrations affiliated to governments that approve or permit such MD product to enter the market of that country (region);

5. Applicable product standards

   In the event that the Chinese national standards or industrial standards are employed, the applicant shall present the text of the employed Chinese national standards industrial standards. In the event that the registered product standards is employed, the applicant shall submit the text of the employed registered product standards with the signature and/or seal of the manufacturer or its representative office located in China or the unit authorized by the manufacturer to have drawn up such standards. In the letter of authorization on drawing up product standards shall be clearly indicated that “The manufacturer shall be responsible for the product quality”.

   The manufacturer shall provide a statement that states the product applied for registration complies with the employed Chinese national standards or industrial standards. In addition, the manufacturer shall provide a statement that states it will bear the quality liabilities after such product are approved for sales, and a statement of explanations on the classification of model and specifications of the products involved.

   “Signature and/or seal” hereof refers to the seal of the organization, or the signature of the legal representative and person chief-in-charge plus, or seal plus signature. (for overseas MD, hereinafter with the same meaning).

6. Instruction of manual of MD

   The instruction of manual of MD under Class II and Class III shall be attached by the signature and/or seal of the manufacturer or its organizations in China. As for the MD under Class I, such signature and/or seal may be left out.

7. A test report on MD applied for registration issued by MD testing institutions (applicable to MD under Class II and Class III)

   For the MD necessary for clinical trials, the applicant shall submit a test report issued by MD testing institutions within half a year prior to commencement of clinical trials. For the MD unnecessary for clinical trials, the applicant shall submit a test report issued by MD testing institutions within one (1) year prior to the acceptance of registration.

   In the event the provisions in Article 11, Article 12, Article 13 or Article 14 are applicable, the applicant shall present the related statement of explanations.

In the event that the situations provided for Article 15 of the Provisions exist, the manufacturer shall file an application for a delayed test, in which the manufacturer must guarantee that a test will be completed prior to initial service of the first MD within the territory of Chinese mainland.

8. MD Clinical Trials Materials (refer to Appendix 12 for details)

9. A statement of guarantee on quality of the product issued by the manufacturer

   The manufacturer shall make a commitment in such a statement that the product to be registered and sold in China will have the same quality as the same product approved for sale by overseas MD administrations affiliated to governments.

10. A letter of authorization which designates agent in China, a letter of commitment and the business license or organization registration certificate of such entrusted agent;

    The contents of the letter of commitment of the agent shall be consistent with the entrusted matters in the letter of authorization of the manufacturer. In addition, such letter of commitment shall include the agent's commitments to report adverse-effect events of MD and to contact with (food &) drug administration.

11. A letter of authorization which designate after-sales service agencies in China, a letter of commitment and the qualification certificates of such entrusted agencies;

    The letter of authorization on after-sales service shall be issued by the manufacturer, and accompanied with the name of the product. In case of multiple-level of entrustments, each level of entrusted organization shall provide a document showing that such entrustment has obtained the consent of the manufacturer.

    The contents of the letter of commitment of the service agencies shall be consistent with the entrusted matters in the letters of authorization.

    The qualification certificates of the after-sales agencies refer to the business license or registration certificate of the manufacturer's organizations located in China.

12. A statement of guarantee on the authenticity of the materials submitted.

    Such statement shall be issued by the manufacturer or its representative offices in China, and shall include a list of the submitted materials and a statement of commitment on assumption of legal responsibilities.

    The above-mentioned documents shall have their Chinese version. The certifying documents mentioned in Item 2 and Item 4 of this Appendix may be submitted in photocopies, but shall be signed and sealed by the original issuing authorities or notarized by local notary offices. Except otherwise stipulated in the Provisions, other documents mentioned in this Appendix shall be submitted in originals with seals or signatures of manufacturer, or the manufacturer's office or representative office in China.

Appendix 7

Materials to Be Submitted When Applying for Re-registration of Overseas MD

1. Application for Overseas MD Registration

2. Qualification certificate of MD manufacturer

3. Original registration certificate of MD

   In the event that the situations provided or in Article 33 in Chapter V of the Provisions exist, the copies of the original registration certificate of MD shall be submitted. In the event that the situations provided or in Article 34 or Article 35 in Chapter V of the Provisions exist, the original registration certificate of MD shall be submitted.

4. Certificate issued by overseas MD administrations affiliated to governments that approve or permit such MD product to enter the market of that country (region);

5. Applicable product standards

   In the event that the Chinese national standards or industrial standards are employed, the applicant shall present the text of the employed Chinese national standards industrial standards. In the event that the registered product standards is employed, the applicant shall submit the text of the employed registered product standards with the signature and/or seal of the manufacturer or its representative office located in China or the unit authorized by the manufacturer to have drawn up such standards. In the letter of authorization on drawing up product standards shall be clearly indicated that “The manufacturer shall be responsible for the product quality”.

   The manufacturer shall provide a statement that states the product applied for registration complies with the employed Chinese national standards or industrial standards. In addition, the manufacturer shall provide a statement that states it will bear the quality liabilities after such product are approved for sales, and a statement of explanations on the classification of model and specifications of the products involved.

6. Instruction of manual of MD

   The instruction of manual of MD under Class II and Class III shall be attached by the signature and/or seal of the manufacturer or its organizations in China. As for the MD under Class I, such signature and/or seal is not compulsory.

7. A test report on MD applied for registration issued by MD testing institutions (applicable to MD under Class II and Class III)

   For the MD necessary for clinical trials, the applicant shall submit a test report issued by MD testing institutions within half a year prior to commencement of clinical trials. For the MD unnecessary for clinical trials, the applicant shall submit a test report issued by MD testing institutions within one (1) year prior to the acceptance of registration.

   In the event the provisions in Article 11, Article 12, Article 13 or Article 14 are applicable, the applicant shall present the related statement of explanations.

   In the event the provisions in Article 10 Item 2 in *Provisions on Registration Test of*

Imported MD are applicable, the applicant shall provide the corresponding certification report.

8. A quality tracking report of product

   The applicant shall present a quality tracking report of product issued by the agent of the manufacturer after the application of such product in Chinese medical units, in which a statement of explanation on adverse-effect events monitoring shall be included.

9. A statement of guarantee on quality of the product issued by the manufacturer

   The manufacturer shall make a commitment in such a statement that the product to be registered and sold in China will have the same quality as the same product approved for sale by overseas MD administrations affiliated to governments.

10. A letter of authorization which designates agent in China, a letter of commitment and the business license or organization registration certificate of such entrusted agent;

    The contents of the letter of commitment of the agent shall be consistent with the entrusted matters in the letter of authorization of the manufacturer. In addition, such letter of commitment shall include the agent's commitments to report adverse-effect events of MD and to contact with (food &) drug administration.

11. A letter of authorization which designate after-sales service agencies in China, a letter of commitment and the qualification certificates of such entrusted agencies;

    The letter of authorization on after-sales service shall be issued by the manufacturer, and accompanied with the name of the product. In case of multiple-level of entrustments, each level of entrusted organization shall provide a document showing that such entrustment has obtained the consent of the manufacturer.

    The contents of the letter of commitment of the service agencies shall be consistent with the entrusted matters in the letters of authorization.

    The qualification certificates of the after-sales agencies refer to the business license or registration certificate of the manufacturer's organizations located in China.

12. In the event that the situation provided for Article 34 in Chapter V of the Provisions exists, a statement of explanations and certifying documents shall be submitted.

13. A statement of guarantee on the authenticity of the materials submitted.

    Such statement shall be issued by the manufacturer or its representative offices in China, and shall include a list of the submitted materials and a statement of commitment on assumption of legal responsibilities.

    The above-mentioned documents shall have their Chinese version. The certifying documents mentioned in Item 2 and Item 4 of this Appendix may be submitted in photocopies, but shall be signed and sealed by the original issuing authorities or notarized by local notary offices. Except otherwise stipulated in the Provisions, other documents mentioned in this Appendix shall be submitted in originals with seals or signatures of manufacturer, or the manufacturer's office or representative office in China.

Appendix 8

Materials to Be Submitted When Applying for Initial Registration of Overseas MD under Class I that Has Not Acquired a Sales Permit for Overseas MD.

1. Application for Overseas MD Registration

2. Qualification certificate of MD manufacturer

3. Applicable product standards

   In the event that the Chinese national standards or industrial standards are employed, the applicant shall present the text of the employed Chinese national standards industrial standards. In the event that the registered product standards is employed, the applicant shall submit the text of the employed registered product standards with the signature and/or seal of the manufacturer or its representative office located in China or the unit authorized by the manufacturer to have drawn up such standards. In the letter of authorization on drawing up product standards shall be clearly indicated that “The manufacturer shall be responsible for the product quality”.

   The manufacturer shall provide a statement that states the product applied for registration complies with the employed Chinese national standards or industrial standards. In addition, the manufacturer shall provide a statement that states it will bear the quality liabilities after such product are approved for sales, and a statement of explanations on the classification of model and specifications of the products involved.

4. A self-test report on performance of the product;

5. A description of the existing resources, conditions and capacity of quality management (including means of test) for the production;

6. Instruction manual of MD (Signature or seal may be left out.)

7. A letter of authorization which designates agent in China, a letter of commitment and the business license or organization registration certificate of such entrusted agent;

   The contents of the letter of commitment of the agent shall be consistent with the entrusted matters in the letter of authorization of the manufacturer. In addition, such letter of commitment shall include the agent’s commitments to report adverse-effect events of MD and to contact with (food &) drug administration.

8. A letter of authorization which designate after-sales service agencies in China, a letter of commitment and the qualification certificates of such entrusted agencies;

   The letter of authorization on after-sales service shall be issued by the manufacturer, and accompanied with the name of the product. In case of multiple-level of entrustments, each level of entrusted organization shall provide a document showing that such entrustment has obtained the consent of the manufacturer.

   The contents of the letter of commitment of the service agencies shall be consistent with the entrusted matters in the letters of authorization.

The qualification certificates of the after-sales agencies refer to the business license (with a business scope covering the required technical service items) or registration certificate of the manufacturer's organizations located in China.

9. A statement of guarantee on the authenticity of the materials submitted.

   Such statement shall be issued by the manufacturer or its representative offices in China, and shall include a list of the submitted materials and a statement of commitment on assumption of legal responsibilities.

   The above-mentioned documents shall have their Chinese version. The certifying documents mentioned in Item 2 of this Appendix may be submitted in photocopies, but shall be signed and sealed by the original issuing authorities or notarized by local notary offices. Except otherwise stipulated in the Provisions, other documents mentioned in this Appendix shall be submitted in originals with seals or signatures of manufacturer, or the manufacturer's office or representative office in China.

Appendix 9

Materials to Be Submitted When Applying for Initial Registration of Overseas MD under Class II and III without Marketing Clearance

1. Application for Overseas MD Registration

2. Qualification certificate of MD manufacturer

3. Product Technical Report

   At least including technical specifications and conditions to confirm main performance, etc.

4. Analysis Report on risks and Safety

   It shall be compiled according to the requirements of YY0316 *Risk Analysis of MD*. Analysis of the following aspects of hazard and their relevant preventive measures shall be included in the report: energy hazard, biology hazard, environment hazard, operation related hazard, and hazard caused by malfunction, bad maintenance and aging.

5. Applicable product standards

   In the event that the Chinese national standards or industrial standards are employed, the applicant shall present the text of the employed Chinese national standards industrial standards. In the event that the registered product standards is employed, the applicant shall submit the text of the employed registered product standards with the signature and/or seal of the manufacturer or its representative office located in China or the unit authorized by the manufacturer to have drawn up such standards. In the letter of authorization on drawing up product standards shall be clearly indicated that “The manufacturer shall be responsible for the product quality”.

   The manufacturer shall provide a statement that states the product applied for registration complies with the employed Chinese national standards or industrial standards. In addition, the manufacturer shall provide a statement that states it will bear the quality liabilities after such product are approved for sales, and a statement of explanations on the classification of model and specifications of the products involved.

6. A self-test report on performance of the product;

   Items demands self-test are those pre-sale test items specified by registered product standards. Chief inspector, inspection director or verifier shall sign the report. When state standard or industry standard is applied, the manufacturer shall add pre-sale inspection items by themselves.

7. A test report on MD applied for registration issued by MD testing institutions

   For the MD necessary for clinical trials, the applicant shall submit a test report issued by MD testing institutions within half a year prior to commencement of clinical trials. For the MD unnecessary for clinical trials, the applicant shall submit a test report issued by MD testing institutions within one (1) year prior to the acceptance of registration.

   In the event the provisions in Article 11, Article 12, Article 13 or Article 14 are applicable,

the applicant shall present the related statement of explanations.

8. Clinical trials files of MD (see Appendix 12 for specific submission method)

9. Instruction manual of MD (it shall be sealed by manufacturer or its agent in China)

10. Valid certificates for quality system examination (certification) on production of product:

    A qualification report of MD production quality system provided by SFDA shall be submitted.

11. A letter of authorization which designates agent in China, a letter of commitment and the business license or organization registration certificate of such entrusted agent;

    The contents of the letter of commitment of the agent shall be consistent with the entrusted matters in the letter of authorization of the manufacturer. In addition, such letter of commitment shall include the agent's commitments to report adverse-effect events of MD and to contact with (food &) drug administration.

12. A letter of authorization which designate after-sales service agencies in China, a letter of commitment and the qualification certificates of such entrusted agencies;

    The letter of authorization on after-sales service shall be issued by the manufacturer, and accompanied with the name of the product. In case of multiple-level of entrustments, each level of entrusted organization shall provide a document showing that such entrustment has obtained the consent of the manufacturer.

    The contents of the letter of commitment of the service agencies shall be consistent with the entrusted matters in the letters of authorization.

    The qualification certificates of the after-sales agencies refer to the business license (with a business scope covering the required technical service items) or registration certificate of the manufacturer's organizations located in China.

13. A statement of guarantee on the authenticity of the materials submitted.

    Such statement shall be issued by the manufacturer or its representative offices in China, and shall include a list of the submitted materials and a statement of commitment on assumption of legal responsibilities.

    The above-mentioned documents shall have their Chinese version. The certifying documents mentioned in Item 2 of this Appendix may be submitted in photocopies, but shall be signed and sealed by the original issuing authorities or notarized by local notary offices. Except otherwise stipulated in the Provisions, other documents mentioned in this Appendix shall be submitted in originals with seals or signatures of manufacturer, or the manufacturer's office or representative office in China.

Appendix 10

Materials to Be Submitted When Applying for Modification of the MD Registration Certificate

1. Requirements on application documents of manufacture name changing:

   (1) Original of MD registration certificate (For application, copy version is needed. To obtain the modified MD registration certificate, the original of the former certificate shall be returned.)

   (2) Latest manufacturer license (applicable to MD under Class II and III)

   (3) Latest business license (applicable to domestic MD)

   (4) Latest legal qualification certificate of the manufacturer (applicable to overseas MD)

   (5) Latest product standard (applicable to manufacturer who has changed the main part of its standard)

   (6) Explanation to modification provided by the manufacturer and certificates concerned

   (7) A statement of guarantee on the authenticity of the materials submitted.

   A list of the submitted materials and a statement of commitment on assumption of legal responsibilities shall be included. Such statement shall be issued by the manufacturer or its representative offices in China if there's modification to the registration certificate of overseas MD.

2. Requirements on application documents of the literal change of product name, product model, product standard and product code:

   (1) Original of MD registration certificate (For application, copy version is needed. To obtain the modified MD registration certificate, the original of the former certificate shall be returned.)

   (2) Latest product standard

   (3) Instruction manual of MD

   (4) Explanation to modification provided by the manufacturer and certificates concerned

   (5) A statement of guarantee on the authenticity of the materials submitted.

   A list of the submitted materials and a statement of commitment on assumption of legal responsibilities shall be included. Such statement shall be issued by the manufacturer or its representative offices in China if there's modification to the registration certificate of overseas MD.

3. Requirements on application documents of the change manufacturer's reiterated address and the literal change of production address:

   (1) Original of MD registration certificate (For application, copy version is needed. To obtain the modified MD registration certificate, the original of the former certificate shall be returned.)

   (2) Latest manufacturer license (applicable to MD under Class II and III)

   (3) Latest business license (applicable to domestic MD)

   (4) Explanation to modification provided by the manufacturer and certificates concerned

   (5) Statement of address changing by the manufacturer (applicable to overseas MD)

(6) A statement of guarantee on the authenticity of the materials submitted.

A list of the submitted materials and a statement of commitment on assumption of legal responsibilities shall be included. Such statement shall be issued by the manufacturer or its representative offices in China if there's modification to the registration certificate of overseas MD.

4. Requirements on application documents of the change of agent in overseas MD registration certificate:

(1) Original of MD registration certificate (For application, copy version is needed. To obtain the modified MD registration certificate, the original of the former certificate shall be returned.)

(2) Agent changing statement provided by the manufacturer

(3) The entrustment paper provided to the new agent

(4) The business license or organization registration certificate after changing

(5) Agent's acceptance of the entrustment and promise to bear relevant responsibilities after changing

(6) A statement of guarantee on the authenticity of the materials submitted.

Such statement shall be issued by the manufacturer or its representative offices in China, and shall include a list of the submitted materials and a statement of commitment on assumption of legal responsibilities.

5. Requirements on application documents of after-sale organization change in overseas MD registration certificate:

(1) Original of MD registration certificate (For application, copy version is needed. To obtain the modified MD registration certificate, the original of the former certificate shall be returned.)

(2) After-sale service organization changing or increase statement provided by the manufacturer

(3) Entrustment paper for after-sale service organization after changing or increase provided by the manufacturer

(4) Manufacturer's management and promise for products sold out

(5) Business license or organization registration certificate of after-sale service organization after changing or increase

(6) After-sale service organization's promise to bear the responsibility of after-sale service after changing or increase

(7) A statement of guarantee on the authenticity of the materials submitted.

Such statement shall be issued by the manufacturer or its representative offices in China, and shall include a list of the submitted materials and a statement of commitment on assumption of legal responsibilities.

Appendix 11

Materials to Be Submitted When Re-applying for MD Registration Certificate

(I) The reasons for re-applying and related explanations.

(II) The qualification certificate of the applicant;

(III) Copies of the original registration certificate & its annexes;

(IV) The statement of commitment on the authenticity of the materials submitted, including the list of submitted materials, Manufacturer's commitment to take legal responsibility. For re-application for registration certificate of overseas MD, this statement shall be issued by the manufacturer or its office set up in China.

Appendix 12

Provisions on Report Items of Clinical Trials for MD Registration

Product Classification	Basic Information	Conditions	Providing of Clinical Trial Information
Class-III Products	I. In any term	Products have not been authorized to come to the market in the foreign country (region) by competent authority of the foreign government.	Information regarding clinical trials carried out in China shall be provided.
Class-III transplantable Products	I. None of the enterprise's products has entered China	Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government.	Information regarding clinical trials carried out in China shall be provided.
	II. Some of the enterprise's products have entered China.	A. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) The enterprise's quality system has been checked and approved by Chinese Government, but it does not cover the product under application.	For products sold in China, relevant clinical trial information shall be provided as required; for products sold overseas, the clinical trial information prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government shall be provided to the Expert Team organized by Chinese Government for verification.

		B. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) The enterprise's quality system recognized by Chinese Government has covered the product under application and is valid; 3) Other products of the enterprise have been sold in China for more than 4 years and have no any complain records. Note: products with a complain record shall comply with provisions under Item A.	For products sold in China, relevant clinical trial information shall be provided as required; for products sold overseas, the clinical trial information prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government shall be provided.
	III. Some of the enterprise's products have entered China. The product under application is a like of the registered product but its type is different.	A. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) The enterprise's quality system has been checked and approved by Chinese Government, but it does not cover such type of the product under application.	For products sold in China, relevant clinical trial information shall be provided as required; for products sold overseas, the clinical trial information prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government shall be provided to the Expert Team organized by Chinese Government for verification.

		B. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) The enterprise's quality system recognized by Chinese Government has covered such type of product under application and is valid; 3) Like products of the enterprise have been sold in China for more than 4 years and have no any complain records. Note: products with a complain record shall comply with provisions under Item A.	For products sold in China, the clinical trial information of like products of this enterprise, prepared at the time when they are approved of registration and coming to the market, shall be provided as required; for products sold overseas, the clinical trial information of like products, prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government, shall be provided.
	IV. Some of the enterprise's products have entered China. The product under application has the same type with the registered product but its specification is different.	A. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) The enterprise's quality system has been checked and approved by Chinese Government, but it does not cover such specification of the product under application.	For products sold in China, relevant clinical trial information shall be provided as required; for products sold overseas, the clinical trial information prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government shall be provided to the Expert Team organized by Chinese Government for verification.

		B. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) The enterprise's quality system recognized by Chinese Government has covered the product under application and is valid; 3) Like products of the enterprise have been sold in China for more than 4 years and have no any complain records. Note: products with a complain record shall comply with provisions under Item A.	For products sold in China, the clinical trial information of like products of this enterprise, prepared at the time of registration and coming to the market, shall be provided; for products sold overseas, the clinical trial information of like products of this enterprise, prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government, shall be provided.
Other Class-III products	I. None of the enterprise's products has entered China.	Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government.	For products sold in China, relevant clinical trial information shall be provided as required; for products sold overseas, the clinical trial information prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government shall be provided to the Expert Team organized by Chinese Government for verification.
	II. Some of the enterprise's products have entered China but it is the first time for the product under application to enter China.	A. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) The products are MD using ultrasonic, microwave, laser, X-rays, gamma rays, and other radioactive particles as therapy sources.	For products sold in China, relevant clinical trial information shall be provided as required; for products sold overseas, the clinical trial information prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government shall be provided to the Expert Team organized by Chinese Government for verification.

		B. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) the products are for diagnosis or do not use ultrasonic, microwave, laser, X-rays, gamma rays, and other radioactive particles as therapy sources; 3) Other products of the enterprise have been sold in China for more than 4 years and have no any complain records. Note: products with a complain record shall comply with provisions under Item A.	For products sold in China, relevant clinical trial information shall be provided as required; for products sold overseas, the clinical trial information prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government shall be provided.
	III. Some of the enterprise's products have entered China. The product under application is a like of the registered product.	A. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) The products are MD using ultrasonic, microwave, laser, X-rays, gamma rays, and other radioactive particles as therapy sources.	For products sold in China, relevant clinical trial information shall be provided as required; for products sold overseas, the clinical trial information prepared at the time when they are approved of registration and coming to the market by the competent authority of the foreign government shall be provided to the Expert Team organized by Chinese Government for verification.
		B. On condition that: 1) Products have not been authorized to come to the market in China but have been authorized to come to the market in the foreign country (region) by competent authority of the foreign government; 2) like products of the enterprise have been sold in China for more than 4 years and have no any complain records. Note: products with a complain record shall comply with provisions under Item A.	The clinical trial information of like products of this enterprise, prepared at the time when they are approved of registration and coming to the market, shall be provided.

Class-II products	I. In any term	Products have not been authorized to come to the market in China, and not been authorized to come to the market in the foreign country (region) by competent authority of the foreign government, either.	Information regarding clinical trials carried out in China shall be provided.
	II. It is the first time for the product to enter China.	A. The product under application has been authorized to come to the market in the foreign country (region) by competent authority of the foreign government.	The clinical trial information of the products, prepared at the time when they are approved of coming to the market by the competent authority of the foreign government, shall be provided.
		B. Like products have been authorized to come to the market in China by Chinese Government.	The clinical trial information and comparison results of like products shall be provided.
		C. The products are MD used for testing and diagnosis and complying with national standards and trade standards.	No clinical trial information is needed.

Notes:

1. The Like Products refer to the products having the same fundamental principle, major functions, structure, material, character, and anticipated purpose. The detailed list shall be prepared and promulgated by the State Food & Drug Administration.
2. Same-Type Products refer to products having the same principle and structure of auxiliary function on the premise of same fundamental principle, major functions, and structure.
3. Same-Specification Products refer to products having the same fundamental principle, major functions, and structure, the same principle and structure of auxiliary function, and the same performance parameter, index, and geometrical size.
4. A complaint refers to the adverse-effect event arousing out of product quality, defined upon technical approaches and handled by the State Food & Drug Administration or food & drug administration department of a province, autonomous region, and municipality directly under the Central Government.
5. For products required providing the information regarding clinical trials carried out in China, the information of clinical trials carried out at two or more clinical trial bases should be provided.