

Brief Introduction of Medical Device Regulations in China

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Part 1

CURRENT REGULATIONS

1. Regulations for the Supervision and Administration of Medical Devices

Decree 276 of the State Council, issued on January 4, 2000, effective since April 1, 2000.

5 chapters, 48 articles, highest medical device regulations.

OUTLINES:

1. Who should Observe?

Any institution or individual engaged in research, manufacturing, distribution, use and administration of medical devices.

2. Definition of Medical Devices:

Similar as most countries.

OUTLINES:

**3. Competent Authority:
SFDA.**

**4. Product Classification:
3 classes.**

**5. Product Standards:
National, industrial, company.**

OUTLINES:

6. Product Registration

7. Licensing of Manufacturers and Distributors

8. Product Reevaluation

9. Post Marketing Surveillance

2. Provisions Governing the Registration of Medical Devices

**Decree 16 of SFDA, issued on August 9, 2004,
effective since the same day.**

9 chapters, 56 articles, plus 12 annexes.

Specific regulations for registration of MD.

“Provisions Governing the Registration of Medical Devices ”

- 1) Previous: Issued by SDA on April 1, 2000, Effective from 20/04/2000 to 08/08/2004;**
- 2) Current: Issued by SFDA and became effective on August 9, 2004**

A Medical Device Registration Certificate

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械注册证
REGISTRATION CERTIFICATE FOR MEDICAL DEVICE

注册号: 国药管械(进)字 2000 第 0130 号
REG. NO: SDA(I)20000130

爱尔兰 Loctite 公司:

你单位生产的 Indermil™组织黏合剂, 经审查, 符合医疗器械产品市场准入规定, 准许注册。自批准之日起有效期四年。

特此证明。

Loctite (Ireland) Limited:
This is to certify that the product (Indermil™ Tissue Adhesive) manufactured by your company has been inspected by our office and is permitted to register on the Chinese market. This registration certificate is valid for four years from the date of issue.

国家药品监督管理局
State Drug Administration
2000年02月01日
注册专用章






附件: 医疗器械产品注册登记表
ATTACHMENT: MEDICAL DEVICE REGISTRATION RECORD

Principal Technical Measures:

- Product Classification**
- Standardization**
- Laboratory Test of Product**
- Clinical Trial of Product**
- Quality System Inspection**

Registration Procedures

(For Products Manufactured outside of China)

- (1) Pre-application Preparation by the Applicant;** 
- (2) Application;** 
- (3) Answering Questions or Adding Data upon Request;** 
- (4) On-site Audit of Quality System of the Product (class III products);** 
- (5) Receiving Registration Certificate or Rejection Notice.** 



Pre-Application Preparation by the Applicant

- A. To Compile a Product Standard: --- Two choices:**
- a. To Decide to use a Chinese national or professional *product standard* when there is one available for this particular kind of product and the applicant is willing to use it;**
 - b. To Compile a *Registration Product Standard (RPS)* for your product when there is not a Chinese standard available for this particular kind of product, or when the applicant is not willing to use the Chinese standard. (be careful, all parameters in your own *RPS* must not be more inferior than the Chinese national or professional standard.)**

Pre-Application Preparation by the Applicant

- B. To Complete Laboratory Test (based on your chosen standard) for the Product at a SFDA Recognized Testing Lab (applicable for class II and III products) ;**
- C. To Conduct Clinical Trial in 2 Hospitals in China (applicable only for implantable products manufactured by a foreign company which has never registered a medical device in China), or to Collect Clinical Data for Your Product (applicable for all other class II and III products);**
- D. To Get all Required Documents Ready for the Application.**



Application

To submit application dossier (12 items) at the Application Acceptance Office:

- Application Form for the registration;**
- Qualification certificate(s) (Business License, etc.) of the applicant (manufacturer);**
- Copy of Business License of the Application Agent and the authorization letter written by the applicant to the agent;**
- Marketing authorization certificate issued by a foreign competent authority to allow the product to be marketed in that country (or Region) as a medical device;**



Application

- Adapted product standard;
- Instruction Manual of the device;
- Product Testing Report issued by a SFDA recognized testing lab (applicable for class II and III products);
- Clinical Test Report or clinical data (according to specific product);
- Product quality guarantee letter of the applicant;



Application

- Authorization letter written by the applicant to a Representing Agent in China, letter of promise written by the Representing Agent, and Business License or Organization Registration Certificate of the Agent;**
- Authorization letter written by the applicant to a responsible Post-marketing Service Agent in China, letter of promise written by the agent, and qualification Certificate of the Agent;**
- Self-Declaration for the authenticity of all submitted items.**



Answering Questions or Adding Data upon Request

When the reviewer of SFDA needs to clarify technical issues or finds the application dossier is insufficient in technical data, the applicant (application agent) may be requested to answer questions or hand-in additional data.



On-site Audit of Product Manufacturing Quality System (class III products)

For class III products, during the registration inspection process, the applicant will receive an on-site audit notice, when the applicant should cooperate with SFDA to arrange a schedule for the audit as soon as possible so as to enable a timely approval of the registration.



Receiving Registration Certificate or Rejection Notice

When registration inspection and approval process is completed, a registration certificate or rejection notice is issued to the applicant.



Additional Information Concerning Drug Containing Devices and IVDs (such as complex catheter, stent, etc.)

Drug Containing Devices: Basic Concepts:

1. A drug containing product of which the major function is as a medical device, but the function is assisted by the drug(s), or has additional function(s) (effects) played by the drug(s), is defined as a drug containing medical device.

2. To protect the safety of patients, all essential aspects of a medical device should not be neglected in pre-marketing examination.



3. Drugs are regulated products in China (as in most of other countries). The drug(s) contained in the device should not escape from regulation.

4. Within SFDA, the Department of Drug Registration is responsible for regulating drugs. However, the drug(s) used with a medical device has a different release & delivery route than being used alone. The unique release route is associated with the combining device, and therefore, the examination and evaluation of the drug(s) can not be separated from the device.

5. Within SFDA, the Department of Medical Devices is responsible for regulating medical devices. A drug containing device, as its major function is as a device and the drug(s) contained is (are) not used alone, is requested to register as a medical device.



6. In evaluation of a drug containing device, the expertise of medical devices and drugs should be utilized jointly. The Technical Evaluation Centre of Medical Devices should invite drug evaluation specialists to work together and ask for their advices before reaching a final technical conclusion of the product.



7. In evaluation of a drug containing device, main aspects of concern are:

- (1) Regular device evaluation requirements;**
- (2) Regular drug evaluation requirements;**
- (3) Special requirements concerning the rationality of the drug-device combination mechanism: ---
Could there be any unknown reaction in the combination? Could any unwanted effect(s) be possibly induced? Etc.**

(Complex catheters and stents are regulated as drug containing devices in China.)



In-vitro Diagnostic Reagents

Regulated additionally.

3. New IVD Regulations

- (1) Provisions Governing the Registration of In-vitro Diagnostic Reagents (Trial), (SFDAM[2007]229) (April 19, 2007)**
- (2) Circular on the Implementation of “Provisions Governing the Registration of In-vitro Diagnostic Reagents” (Trial), (SFDAO[2007]230) (April 19, 2007)**



**(3) Provisions Governing the Implementation of Examination of Quality Management System of In-vitro Diagnostic Reagents (Trial);
Detailed Rules on Manufacturing of In-vitro Diagnostic Reagents (Trial);
Evaluation Criteria on Examination of Quality Management System of In-vitro Diagnostic Reagents (Trial);
(SFDAM[2007]239) (April 28, 2007)**



**(4) Principles on the Technical Guidance of Clinical
Study of In-vitro Diagnostic Reagents;
Principles Guiding the Compiling of Instruction
Manual of In-vitro Diagnostic Reagents;
(SFDAM[2007]240) (April 28, 2007)**

Part 2

BRIEFING ON REVISION OF THE “REGULATIONS FOR THE SUPERVISION AND ADMINISTRATION OF MEDICAL DEVICES”

1. Why to Revise?

First set of medical device regulations issued by State Council;

Has played an import role in strengthening and standardizing the supervision and administration of MD in China;

Considerably good results have been achieved in the 7 years; However,

Development of the national economy, deepening of reform, heightening of lawful administration requirements;

Formulated and issued 7 years ago and not fully adaptable to current need.

Main existing problems:

Registration system;

Relations between regulations and standards;

Overlap of responsibilities;

Not systematic enough and not detailed enough;

Not enough penalties;

Etc.

2. Progress

Start: 2nd half of 2006;

SFDA departments involved: Department of Policy and Regulations, Department of Medical Devices, Department of Drug Market Surveillance;

Beginning 2007: Task study done;

End of March 2007: Basic ideas formed;

End of July 2007: First draft completed;

Aug. and early Sep.: Discussion and revision of FD;

Sep. 21, 2007: Put on internet for public opinion.

www.sfda.gov.cn

Thank you very much.