Changing your Manufacturing Site

Implications and Procedures for Updating your

existing SFDA Registration in China

CONTENTS

INTRODUCTION

Any changes to your current manufacturing site address will impact both existing and future SFDA sales and marketing approvals.

Goods manufactured in the new facility **cannot be sold** in China until the new submission is approved. Sale of goods manufactured in the old facility may continue.

A number of documents must be submitted to SFDA to inform them of this change.

In addition, documents provided to SFDA previously in order to gain sales and marketing approval must be revised.

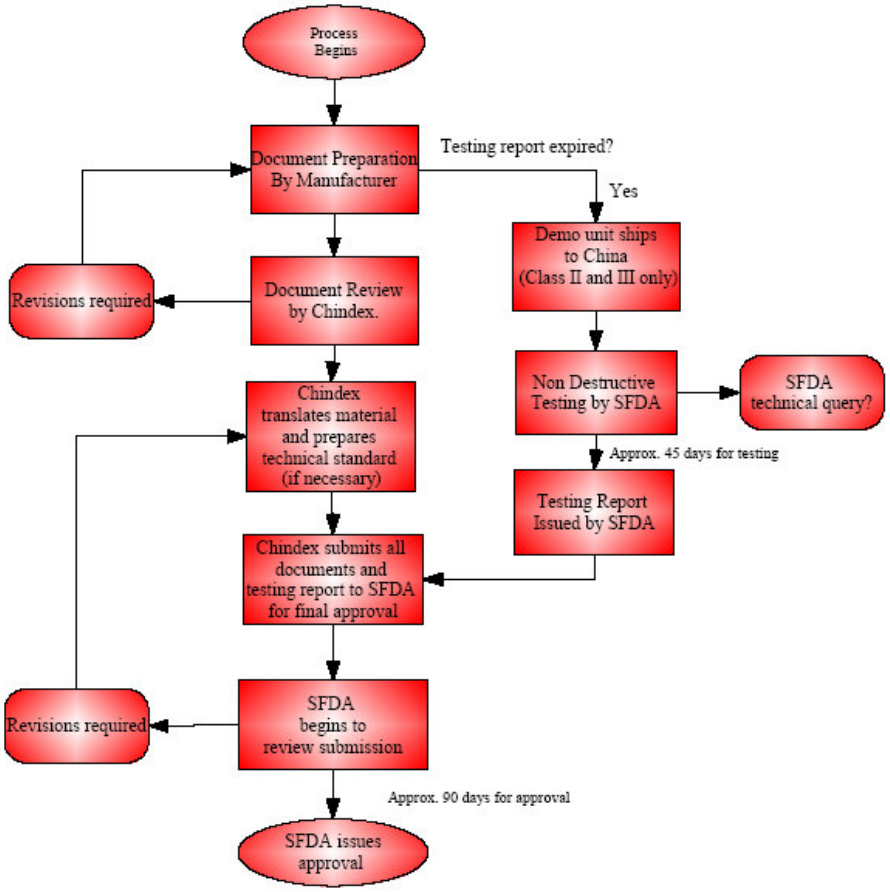
As you may be aware medical devices classified as Class II or III must undergo type testing in China as part of the standard approval process. The result of this testing is the issuance of a testing report.

This testing report must be resubmitted to SFDA for the 'change of manufacturing site' process. However testing reports are only valid for a period of one year after issuance. If your testing report has expired it will be necessary to conduct new type testing at a SFDA facility for which a demo unit will be required.

SFDA SUBMISSION REQUIREMENTS

The overall time taken to complete this process may vary depending on the time taken to collect all necessary documentation, delays due to revisions required by SFDA and the overall workload of SFDA officials.

The SFDA submission process for modifying an existing SFDA marketing approval is shown below.



COST OF SFDA SUBMISSSION

In order to ensure timely revision of the existing registration we recommend that the process is begun a minimum of 10 months before you plan to begin supplying goods manufactured in the new facility. If your testing report is still valid then this estimation may be reduced.

The cost to revise the registration of a medical device will depend on the type, complexity of the MD, and the whether new type testing is required.

We expect that the maximum average cost will not exceed $2000-3000.

Approximate costs can be broken down as:

- *SFDA Registration fee*: RMB3,000
- *Type Testing Fee*: RMB2,000 – 18,000 (if required)
- *Shipping fees for testing demo units*: Deposit -30% of goods value; Freight expenses – RMB103/kg; Service Fee – 0.7% of deposit; Customs service fee – RMB500

DOCUMENTATION REQUIREMENTS

The submission to SFDA must include a range of documents.

These materials confirm the manufacturer's eligibility to produce and market the device in their home country, demonstrate the technical capabilities and functions of the unit, show that the manufacturer maintains Quality System compliance, and provides authorization for Chindex to act as your agent during the registration process.

The submission documents will provide evidence of the change in manufacturing site location.
The chart on the page below provides an itemized checklist of the documents that should be compiled by your organization and provided to Chindex as soon as possible.

Suggested format of documents and notarization / signatory requirements apply in some cases.

Additional clarification on each item follows the chart.

Chindex will submit additional documents drawn from material completed for your original registration submission. If Chindex did not complete the original submission on your behalf and these documents are no longer available, supplemental documentary requirements may apply.

Please note that a separate set of documents must be supplied for each registration you wish to revise.

Document To Be Provided	*Samples Available*	*Preferred Format*	*Special Considerations*
(1)Annual Registration / Business License / Certificate of Registration of a Private Company		Hardcopy	Please see section on notarizations below.
(2) Certificate to Foreign Government / Free Sales Certificate		Hardcopy	Please see section on notarizations below
(3) All user and technical manuals (English)		Electronic copy and hardcopy of 1st page	Please provide signed hardcopy of first page of manuals
(4)) EN ISO 9001 / EN ISO 13485 certificate		Electronic copy	Please see section on notarizations below
(4) Letter of Proxy	✓	Hardcopy	Please print on letterhead and sign
(5) Letter of Guarantee of Quality	✓	Hardcopy	Please print on letterhead and sign
(6) Letter of After-Sales Service Authorization	✓	Hardcopy	Please print on letterhead and sign
(7) Letter of Legal Agent Entrustment	✓	Hardcopy	Please print on letterhead and sign
(8) Declaration of Standard	✓	Hardcopy	Please print on letterhead and sign
(9) Declaration of Authenticity of Materials	✓	Hardcopy	Please print on letterhead and sign
(10) Change of Manufacturing Site Statement	✓	Hardcopy	Please print on letterhead and sign

DETAILED DESCRIPTION OF DOCUMENTS:

1. Annual Registration / Business License / Certificate of Registration of a Private Company – please provide a notarized, valid, hardcopy of this document for each of your applicable manufacturing facilities. [INCLUDING NEW MANUFACTURING ADDRESS]

2. Certificate to Foreign Government / Certificate of Free Sale - please provide an original hardcopy or notarized photocopy of the free sales certificate. [INCLUDING NEW MANUFACTURING ADDRESS]

3. All User and Technical Manuals – please provide electronic copies of your English language manuals. In addition we require a hardcopy of the first page of the manual signed by you.

4. EN ISO 9001 / EN ISO 13485 certificate – SFDA recognizes the importance of Good Manufacturing Practices and Quality System compliance. Although compliance with the ISO 9001 / ISO 13485 standards does not exempt a manufacturer from completing type testing in China it is useful to demonstrate adherence to GMP. Please provide notarized copies of your ISO 9001 or ISO 13485 certificates.

5. Letter of Proxy – this letter entrusts Chindex with the rights to develop the 'technical standard' document that is required for type testing and approval. Please see the sample in the appendix. A hardcopy original on signed letterhead is required.

6. Letter of Guarantee of Quality – this letter confirms that the product to be registered and sold in China will be of equal quality to those same products sold in the manufacturer's home country. Please provide a hardcopy signed

original of the letter on corporate letterhead. A sample can be found in the appendix.

7. Letter of After-Sales Service Authorization – SFDA requires that the manufacturer designate the party which will be responsible for conducting after-sales service. We have prepared a sample letter in the appendix.

8. Letter of Legal Agent Entrustment – this document appoints Chindex to be the legal agent of the manufacturer regarding governmental and market issues in China. A sample of this document can be found in the appendix and should be provided in original hardcopy form on corporate letterhead.

9. Declaration of Standard - as two copies of the 'technical standard' must be submitted to SFDA, it is required that a declaration is made to confirm that both copies are identical. As sample of this letter can be found in the appendix.

10. Declaration of Authenticity of Materials – this letter lists all documents provided by manufacturer to SFDA and vouches for their authenticity. The contents of this list may vary slightly according to registration, but a typical selection is shown in the sample document in the appendix. Please provide a signed hardcopy original printed on corporate letterhead.

11. Change of Manufacturing Site Statement – this letter confirms to SFDA that your manufacturing site has changed location. A sample of this statement can be found in the appendix. Please provide a signed hardcopy original printed on corporate letterhead.

NOTARIZATION OF DOCUMENTS

- Copies of documents must be notarized by one of two methods**:**

    1. Prepare a notarized cover letter that includes a seal and ribbon that is clearly attached to all pages of the copied document.
    2. Stamp every page of the copied document with the notary seal.

- Only the following documents need to be notarized:
    1. Annual Registration / Business License / Certificate of Registration
    2. Certificate to Foreign Government / Certificate of Free Sale
    3. EN ISO 9001 / EN ISO 13485 Certificate

SIGNATURE ON DOCUMENTS

Please ensure that the following documents are signed prior to submission to Chindex:

- <u>All Manuals</u> (**cover page to be signed**) - Chindex will sign every page of the Chinese translation
- Registration Entrustment Letter
- Letter of Proxy
- Letter of Guarantee of Quality
- Letter of After-Sales Authorization
- Letter of Legal Agent Entrustment
- Declaration of Standard
- Declaration of Authenticity of Materials
- Change of Manufacturing Site Statement

TYPE TESTING

The submission to SFDA must include a testing report (class I products are exempt from this provision). You will recall that during your original SFDA registration process, your device underwent type testing and received a testing report.

In China, the testing report is valid for a period of one year. If your original testing report was issued within this timeframe then you may waive this requirement. However if more than one year has passed, you will be required to undergo the type testing process again.

"Type testing" refers to the process of testing a sample of each product to confirm its safety and efficacy.

The SFDA has established 10 testing centers, each of which specializes in different types of products. Manufacturers are responsible for providing a complete machine (or number of samples) for testing. Although type testing involves non-destructive testing, damage and even complete loss of the unit cannot be ruled out.

Type testing is mandatory for almost all class II and III devices. Class I medical devices are not required to undergo type testing. Testing is conducted in accordance with information in the 'technical standard' and applicable Chinese national standards.

The number of demo units or samples required for testing will vary and be dependent on the size and specifications of the device. Generally if the device is very large one demo unit will be sufficient.

On average type testing is completed within 45 days.

IMPORTANT REGISTRATION INFORMATION

If ANY of the following circumstances arise you must inform Chindex immediately.

- Formal change to the name of your company
- Change to the marketed name of your device
- Another change to the location of your manufacturing facility
- Any technical changes to the device

These occurrences may necessitate an amendment to the existing SFDA registration certificate or the **halt of sales** and need for a new SFDA submission.

Thank you for your attention.

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