



<Provisions for the Instructions, Labels and Package of Medical Devices>

Provisions of the State Food and Drug Administration (SFDA),
No.10 Order of SFDA

On July 8, 2004, Zheng Xiaoyu, Commissioner of the State Food and Drug Administration (SFDA), signed the No.10 Order of SFDA---Provisions for the Instructions, Labels and Package of Medical Devices, which shall go into effect as of the date of promulgation.

The Provisions sets out clear regulations governing the formats, contents, management etc. of the instructions, labels and package of medical devices.

Zheng Xiaoyu
July 8, 2004

Provisions for the Instructions, Labels and Package of Medical Devices

Article 1 These provisions are formulated in accordance with the <Medical Device Supervision Administration Regulation > for the purpose of standardizing the Instructions, Labels and Package of Medical Devices.

Article 2 All the medical devices sold and used within the territory of the People's Republic of China shall be subject to provide the Instructions, Labels and Package in accordance with this provision. Easy-to-use medical device, you may provide one or two from Instructions, Labels and Package in accordance with SFDA's provisions.

Article 3 The user should use the medical device according to the description of instructions.

Article 4 The manufacturer makes the instructions of medical device and provides it to the user with product together. The instruction covers the general information about safety and effect and guide to correctly install, test, operate, use as well as maintain.

The label of medical device is attached on the product or package. It covers the words, figures, symbols which used to identify product characters.

Packing mark on the package is that the words, figures or symbols are used to identify technical characters.

Article 5 The information from Instructions, Labels and Package of medical device should be true, complete, correct, and scientific. And the information is in conformity with product characters. The information of labels and Packing mark should be in conformity with the instructions.

Article 6 The words from the Instructions, Labels and Package are written in Chinese. The manufacturer may append other language. Chinese language used in compliance with standardized.

the words, symbols, table, figures, picture, etc of the Instructions, Labels and Package of medical device should be correct, clear and canonical.



Article 7 The instruction of medical device should be in accordance with the requirement of the national standard or industry standard. It should be included as following:

1. Product name, models and specification
2. Manufacturer's name, address, manufacture address, contact information as well as after sales service representation's name, address and contact information
3. The number of the certificate of medical device
4. The number of the technical standard
5. Product Performance, main structures and Indications for use
6. Contraindication, Precautions and Warnings
7. Interpretation of the figures, symbols, abbreviations, etc. of the labels and marks
8. Illustration and graphic expression of the Operation or installation.
9. Maintenance methods and Storage conditions
10. The method of sterilization and shelf-life (if required)
11. The content which are required in the technical standard

Article 8 The Labels and Package of Medical Devices should be included as following:

1. Product name, models and specification
2. Manufacturer's name, address, manufacture address, contact information
3. The number of the certificate of medical device
4. The number of the technical standard
5. The date of manufacture or lot number
6. Power, voltage, frequency, current and so on
7. The method of sterilization and shelf-life (if required)
8. The figures, logos or other information based on product Characteristic

Article 9 the following information can't be included in the Instructions, Labels and Package

1 Assertion or commitment expressions, such as "with best curative effect", "promise for cure of disease", "guarantee to cure disease", "radical cure", "immediate effect", "no side effect at all".

2 Expressions including "the most advanced technology", "most scientific" "most advanced" "best" etc.

3 Where cure rate or effective rate is indicated

4 Comparison with other enterprises in its safety and effect

5 Commitment expressions including "guaranteed by insurance company", "refund if invalid"

6 Where any company or person prove or recommend the product's effect

7 Where make people feel they have gotten some kind of disease or if without use of this product, he will get illness or his health condition will become worse.

8 Other information forbidden by law or regulations.



Article 10 The name of medical device should be in compliance with relative Chinese standard or provisions

Article 11 The name of medical device should be clearly and prominently displayed on the Instructions, Labels and Package.

Article 12 Trade name may be displayed on the Instructions, Labels and Package, if any. Trade name should be in conformity with the registration certificate for medical device. The general name and trade name can't be displayed on one line. Font sizes of the trade name can't more than general name two times.

In trade name, no absolute expressions that exaggerate product effect or information that not consistent with other laws or regulations are allowed.

Article 13 Precautions, warnings and implications in product manual include the following:

- (1) Any side effect that may happen.
- (2) Protective or emergency, corrective measures taken by operators or users if an accident happens during normal operation
- (3) Disinfection or sterilization methods if applicable
- (4) For products that have been sterilized, sterilization method and a note including "have been sterilized" shall be marked. A measure when package damaged shall be included.
- (5) For product shall be sterilized before use, the disinfection or sterilization method shall be indicated.
- (6) Where a medical device shall be jointly installed or used with other products, requirement for conjunction use shall be included.
- (7) Immunity that may happen with other products or proper danger in use
- (8) Where a product shall be disposed, a disposal method shall be indicated.
- (9) Other precautions for operators or users in accordance with product characteristics

Article 14 Installation information shall ensure a proper installation by operator or user, which includes:

1. Installation introduction, diagram, technical gram
2. Environmental condition for proper installation or technical information which determine whether installation correctly or not
3. Other special installation requirements

Article 15 Instructions for use shall be submitted to SFDA for review in registration application in conformity with *Regulation for Registration of Medical Device*. The content of instructions for use should be in accord with other application document.

Article 16 The manufacturer shall be responsible for authenticity and integrity of instructions for use.



Article 17 Instructions for use which have been reviewed by SFDA shall not be modified or changed.

Article 18 In the case that the modification of instructions for use involves in the renewal regulations in *Regulation for Registration of Medical Device*, it shall not be applied according to regulations for instructions modification.

Article 19 Where the modified information of instructions for use doesn't involve in technical aspect, the manufacturer shall submit relevant document to SFDA and give written notice to the original approval department. The document includes;

- (1) Copy of instructions for use that have been reviewed and reported to SFDA for record.
- (2) The new instructions for use
- (3) Modification description including comparison list
- (4) Relevant modified document for product standard (just limited to literal change)
- (5) Authenticity declaration

Where no written notice is issued by the original approval department in 20 days since receiving modification notice from the manufacturer, the new instructions for use will be valid and reported for record. Where a written notice is issued by the original approval department, the manufacturer shall prepare new document according to the written notice.

Article 20 In the following cases, the drug regulatory authority of governments above county level will issue an warning, followed with an order to correct and keep it in archive.

- (1) where change instructions for use reviewed and recorded without notice
- (2) in the cases that label and package for marketed product conflict with instructions for use or other requirements in this provision
- (3) Where product name or trade name is against with this provision
- (4) Where instructions, label and package are not provided according to this regulation; with the exception of simple and easy-to-use product or stipulated by SFDA.

Article 21 If the manufacturer make an unauthorized change main use or indications of instruction, the manufacturer shall be punished by the local food and drug administration authority at county level or above in accordance with the 35th article of <The Provisions for the Instructions of Medical Devices> which it equates without registration certificate for medical device.

Article 22 The SFDA shall be responsible for the interpretation of these provisions.

Article 23 These provisions come into force upon promulgation. <The Provisions for the Instructions of Medical Devices> promulgated by the SFDA on January 4th, 2002 shall be abolished at the same time.