Administrative Provisions on Instructions for Use and Labels of Medical Devices[1]

Authority: **China FDA (dissolved)**

Document Number: Order No. 6 of the China Food and Drug Administration

Promulgation Date: July 30, 2014

Effective Date: October 1, 2014

Article 1

These Provisions are formulated in accordance with the *Regulations on the Supervision and Administration of Medical Devices* for the purpose of regulating instructions for use and labels of medical devices and ensuring the safe use of medical devices.

Article 2

All medical devices sold or used within the territory of the People's Republic of China shall be accompanied by instructions for use and labels that comply with these Provisions.

Article 3

The term "instructions of medical devices" refers to those technical documents that are formulated by medical device registrants or the parties undergoing recordation of medical devices and are provided for users together with products, and can cover the basic information about the safety and validity of products and be used for guiding the correct installation, debugging, operation, use, repair and maintenance of products.

The label refers to written descriptions, graphics, or symbols affixed to the medical device or its packaging for the purpose of identifying product characteristics and indicating safety warnings or other relevant information.

Article 4

The contents of instructions for use and labels shall be scientific, truthful, complete, and accurate, and shall be consistent with the characteristics of the product.

The content of the instructions for use and labels shall be consistent with the contents approved or filed during registration or record filing.

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

The content of the label shall correspond with the relevant content in the instructions for use.

Article 5

Descriptions in the instructions for use and labels regarding disease names, technical terminology, and diagnostic or therapeutic procedures and outcomes shall use standardized terms as officially issued or regulated by the State. Units of measurement shall conform to national standards.

Article 6

Symbols or identification colors used in instructions for use and labels shall conform to national standards; where no such standards exist, explanations of the symbols and identification colors shall be provided in the instructions for use.

Article 7

Each smallest sales unit of a medical device shall be accompanied by an instruction for use. Users of medical devices shall use the products in accordance with the instructions for use.

Article 8

The product name of a medical device shall be the generic name, and such name shall conform to the naming rules issued by the China Food and Drug Administration. For Class II and Class III medical devices, the product name shall be consistent with that in the medical device registration certificate.

The product name shall be prominently displayed in the instructions for use and on the label.

Article 9

The textual content of the instructions for use and labels shall be in Chinese, and such Chinese shall comply with the national standard language and script norms. Other languages may be provided additionally, but the Chinese version shall prevail.

All text, symbols, tables, numbers, and graphics in the instructions for use and labels shall be accurate, legible, and standardized.

Article 10

The instructions for use shall generally include the following:

1-Product name, model, and specifications;

2-Name, address, and contact information of the registrant or record-filing entity, and for imported medical devices, also the name, address, and contact information of the agent;

3-Name, address, production site, contact information, and manufacturing license or filing certificate number of the manufacturer; where production is contracted, information of the entrusted manufacturer shall also be included;

4-Registration certificate number or record-filing certificate number;

5-Number of the product technical requirements;

6-Product performance, main structure or composition, and intended use;

7-Contraindications, precautions, warnings, and other notices;

8-Installation and usage instructions or diagrams; for consumer-use devices, additional safety instructions shall be provided;

9-Product maintenance and care instructions, and any special storage and transportation conditions and methods;

10-Date of manufacture, service life or expiration date;

11-List of accessories, including components, attachments, consumables, replacement cycles, and methods;

12-Explanation of graphics, symbols, abbreviations, etc., used on the label;

13-Date of preparation or revision of the instructions for use;

14-Other content that should be indicated.

Article 11

The precautionary, warning, and advisory content in the instructions for use shall include:

1-Intended user population;

2-Potential safety hazards and usage limitations;

3-Protective measures and emergency/corrective actions in case of unexpected events during proper use;

4-Necessary monitoring, evaluation, and control methods;

5-Markings for single-use devices and sterilized products, including sterilization method and handling of damaged packaging; where pre-use disinfection or sterilization is required, the relevant method must be described;

6-If the device must be used in combination with other devices, the combined devices' requirements, usage methods, and precautions must be stated;

7-Possible interference with or harm from other products during use;

8-Possible adverse events or side effects due to the product or its ingredients;

9-Disposal methods and environmental considerations post-use;

10-Any other matters that operators or users should be alerted to, based on product characteristics.

Article 12

For reusable medical devices, the instructions for use shall specify the reprocessing procedures, including cleaning, disinfection, packaging, sterilization methods, and the number of permissible reuse cycles or other limitations.

Article 13

Labels shall generally include the following:

1-Product name, model, and specifications;

2-Name, address, and contact information of the registrant or record-filing entity, and for imported products, also of the agent;

3-Registration certificate number or record-filing certificate number;

4-Name, address, production site, contact information, and manufacturing license or filing certificate number of the manufacturer; for contract production, also include entrusted party information;

5-Date of manufacture and service life or expiration date;

6-Power connection conditions and input power;

7-Applicable symbols and other relevant information according to product characteristics;

8-Necessary warnings and precautions;

9-Special storage or operational conditions;

If environmentally hazardous, a warning sign or Chinese warning text must be included;

If radiative or radioactive, a warning sign or Chinese warning text must be included.

Where label size or location prevents full disclosure of the above, at minimum, the product name, model, specification, date of manufacture, and expiration date must be stated, along with a statement: "For other content, see instructions for use."

Article 14

Instructions for use and labels must not contain:

1-Claims such as “best efficacy,” “guaranteed cure,” “cure-all,” “radical cure,” “immediate effect,” “completely free of side effects,” or other efficacy assertions or guarantees;

2-Absolute terms such as “most advanced technology,” “most scientific,” “state-of-the-art,” or “best”;

3-Claims about cure rates or effectiveness rates;

4-Comparisons with other companies’ products regarding efficacy or safety;

5-Promises such as “insured by insurance company,” “money-back guarantee”;

6-Endorsements or testimonials by organizations or individuals;

7-Misleading claims implying or inducing fear of disease without use, or suggesting deterioration of health if not used, or any false, exaggerated, or deceptive content;

8-Any content prohibited by laws or regulations.

Article 15

Instructions for use shall be submitted by the applicant during registration or filing with the Food and Drug Administration. The contents shall be consistent with the materials submitted for registration or filing.

Article 16

For registered devices, no unauthorized changes may be made to the instructions for use.

If registration items are changed, the applicant must revise the instructions for use and label accordingly upon receiving the change approval document.

If other content in the instructions is changed, the applicant must notify the registration authority in writing, and submit comparative documentation. If the authority does not object within 20 working days of receipt, the changes shall take effect.

Article 17

For filed medical devices, if any information in the filing form, technical requirements, or instructions for use changes, the record-filing entity shall revise the instructions and label accordingly.

Article 18

Violations of these Provisions shall be subject to penalties by the food and drug administration authority at or above the county level in accordance with Article 67 of the *Regulations on the Supervision and Administration of Medical Devices*.

Article 19

These Provisions shall come into force on October 1, 2014.

The *Provisions on the Administration of Instructions for Use, Labels and Packaging Markings of Medical Devices* promulgated on July 8, 2004 (Order No. 10 of the former State Food and Drug Administration) shall be repealed simultaneously.