Regulation on Medical Device Instructions and Labels (No. 6 Order of China Food and Drug Administration)

Published on July 30, 2014

Order of China Food and Drug Administration

No. 6

Regulation on Medical Device Instructions and Labels has been approved in the executive meeting of China Food and Drug Administration held on June 27, 2014, and is hereby published. The regulation will come into effect on October 1, 2014.

Director Zhang Yong

July 30, 2014

Regulation on Medical Device Instructions and Labels

Clause 1 To regulate medical device instructions and labels and ensure safe use of medical devices, this regulation is established based on Regulation on Supervision and Administration of Medical Devices.

Clause 2 All medical devices distributed and used in the territory of the People's Republic of China should be supplied together with instructions and labels according to this regulation.

Clause 3 Medical device instructions refer to basic information concerning product safety and effectiveness that is prepared by a medical device registrant or filer and supplied together with the product to users. They are technical documents used to guide proper installation, commissioning, operation, use, maintenance, and servicing.

Medical device labels refer to illustrative text, figures, and symbols attached to a medical device or its package for identification of product features or indication of relevant information such as safety caution.

Clause 4 The content of medical device instructions and labels should be logic, true, complete, accurate, and consistent with product features.

The content of medical device instructions and labels should be consistent with relevant registered or filed information.

The content of medical device labels should coincide with instructions.

Clause 5 Description about disease name, terminology, and diagnosis and treatment process and results contained in medical device instructions and labels should use national standard or normative terms and measurement units in accordance with relevant national standards.

Clause 6 The symbols or identification colors used in medical device instructions and labels should comply with relevant national standards. In absence of such standards, the symbols and identification colors should be described in instructions.

Clause 7 The minimum sales units of medical devices should be supplied with instructions.

Medical device users should use such devices according to the instructions.

Clause 8 Medical device products should use generic names, which should follow the medical device naming rules established by China Food and Drug Administration. The production name of a Class II or Class II medical device should be the same as that given in the medical device registration certificate.

The product name should be marked clearly and prominently in the instructions and on the labels.

Clause 9 The text in medical device instructions and labels should be Chinese in accordance with national language norms. Other languages can be added to medical device instructions and labels, provided that Chinese text should prevail.

Text, symbols, tables, numbers, and figures in medical device instructions and labels should be accurate, clear, and standard.

Clause 10 Generally, medical device instructions should contain the following information:

(1) Product name, model, specification;

(2) Registrant or filer name, address, contact information, and after service organization. For imported medical devices, name, address, and contact information of the agent are also required;

(3) Manufacturer name, address, production site, contact information, and production license number or production filing certificate number. For entrusted production, name, address, production site, and production license number or production filing certificate number of the entrusted enterprise should also be provided;

(4) Medical device registration certificate number of filing certificate number;

(5) Product technical requirements number;

(6) Product performance, main structures or compositions, applicable range;

(7) Contraindications, notices, cautions, and notes;

(8) Installation and operation instructions or illustrations. For medical devices to be used independently by consumers, special notes for safe use should also be provided;

(9) Product maintenance and servicing methods, special storage and transport method;

(10) Service life or expiry date;

(11) List of components, including description about interval and methods for replacing components, accessories, and consumables;

(12) Explanation of the figures, symbols, and abbreviations used on medical device labels;

(13) Production or revision date of the instructions;

(14) Other information to be marked.

Clause 11 Notices, cautions, and notes in medical device instructions mainly include the following:

(1) Product target users;

(2) Potential safety hazards and use limitations;

(3) Operator and user protection measures and emergent and corrective measures to be taken in case of an accident during proper use of the product;

(4) Necessary monitoring, evaluation, and control measures;

(5) Disposable products should be marked with "Disposable" text or symbol. For sterile products, sterilization method and the way to handle damaged sterile package should be indicated. For products requiring disinfection prior to use, the corresponding disinfection or sterilization method should be indicated.

(6) For a product to be installed or used in combination with other medical devices, the requirements, methods, and precautions for such combination should be indicated;

(7) Possible disturbances with other products during use and resulting hazards;

(8) Adverse events that may arise during use of the product or ingredients or auxiliary materials contained in the product that may cause side effects;

(9) Precautions for disposal of waste medical devices. For products requiring treatment after use, the corresponding treatment method should be indicated;

(10) Other notices for the operators and users depending on product features.

Clause 12 For medical devices to be used repeatedly, the treatment methods for re-use should be clarified in the instructions, including methods for cleaning, disinfection, packing, and sterilization as well as allowed number of re-use times or other restrictions.

Clause 13 Generally, medical device labels typically contain the following information:

(1) Product name, model, specification;

(2) Registrant or filer name, address, and contact information. For imported medical devices, name, address, and contact information of the agent are also required;

(3) Medical device registration certificate number of filing certificate number;

(4) Manufacturer name, address, production site, contact information, and production license number or production filing certificate number. For entrusted production, name, address, production site, and production license number or production filing certificate number of the entrusted enterprise should also be provided;

(5) Production date, service life, or expiry date;

(6) Power supply connection conditions and power input;

(7) Figures, symbols or other relevant information to be marked depending on product features;

(8) Necessary cautions and notes;

(9) Special storage and operation conditions ore relevant description;

(10) For medical devices that may cause harmful or negative impact on environment, the labels should contain appropriate cautions or Chinese warnings;

(11) For medical devices with ray emission or radiation function, the labels should contain appropriate cautions or Chinese warnings.

If it's not possible to indicate all of the above information on a medical device label due to limited location or size, at least product name, model, specification, production date, service life or expiry date should be indicated, and "See Instructions for Other Details" should be added to the label.

Clause 14 Medical device instructions and labels should not contain the following:

(1) Affirmative or promissory statement about efficacy of the product such as "best treatment effect", "healing guaranteed", "sure to cure", "cure once and for all", "immediately take effect , or "completely without toxic and side effects";

(2) Absolute description or expression such as "most advanced technology", "best science", or "best of the class";

(3) Statement about cure rate or effective rate;

(4) Comparison with competitor products in terms of efficacy and safety;

(5) Commitment language such as "covered by insurers" or "total refund if not cured";

(6) Use the name or image of any organization or individual as proof or for recommendations;

(7) Misleading description that may make readers feel that they are already suffering from a disease or that ignorance of the medical device will possibly lead to or aggravate a disease, and other false, exaggerated, or misguiding information;

(8) Other information forbidden by laws and regulations.

Clause 15 Medical device instructions should be submitted by registration or filing application to the responsible food and drug administration authority for inspection during registration or filing procedures. The submitted instructions should coincide with other registered or filed documents.

Clause 16 Instructions for medical devices should not be altered without permission after registration review by the responsible food and drug administration authority.

For any registration change to a registered medical device, the applicant should, after obtaining the modification document, modify the instructions and labels according to the modification document.

Any other change to the instructions should be reported to the medical device registration approving authority in written, and relevant documents including comparison between original and modified instructions should be provided. If the approving authority fails to deliver a notice denying such a modification within 20 working days after receiving the said written report, the change to the instructions will become valid automatically.

Clause 17 For a filed medical device, if any change occurs to the information in the filing form, technical requirements for the filed products, or other information in the instructions, the filer should modify the instructions and labels accordingly by itself.

Clause 18 For instructions or labels non in compliance with this regulation, responsible food and drug administration authorities on county or higher level will impose a penalty according to Clause 67 of Regulation on Supervision and Administration of Medical Device.

Clause 19 This regulation will come into effect on October 1, 2014. The Regulation on Medical Device Instructions, Labels, and Packing Identifications issued on July 8, 2004 (formerly No. 10 order of China State and Food Administration) will be annulled on the very same day.