Fédération Européenne de l'Industrie de l'Optique et de la Mécanique de Précision

European Federation of Precision Mechanical and Optical Industries

Europäische Industrie-vereinigung Feinmechanik und Optik

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EUROM VI "Medical Technology"
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Enhancing the health of the public European wide and world wide and
Facilitating innovation by harmonising the European and global regulatory environment

Berlin, 2013-06-17

Proposed Rule: Use of Certain Symbols in Labeling

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 601, 801, and 809
Docket No. FDA-2013-N-0125
RIN 0910-AG51
Use of Certain Symbols in Labeling (Proposed Rule)
AGENCY: Food and Drug Administration, HHS.

EUROM VI Medical Technology as a European industry federation mainly representing small and medium sized enterprises welcomes the opportunity to provide information on FDA's proposed rule regarding the Use of Certain Symbols in Labeling.

EUROM VI Medical Technology highly appreciates and supports FDA's initiative to allow for the use of certain symbols in the labeling of medical devices, if they have been established as part of a standard developed by nationally or internationally recognized standards development organizations, provided that the corresponding standard has been recognized by the FDA, and the symbols used are explained in a symbols glossary that "contemporaneously accompanies" the medical device.

Allowing for the use of certain symbols in the labeling of medical devices according to the above mentioned restrictions, without the symbols being accompanied by explanatory English text adjacent to the symbol …

- will be a step forward to harmonization of regulatory requirements on medical devices, especially regarding the US and EU markets;

- will reduce the efforts of domestic and foreign manufacturers of medical devices to provide separate labels for the US market and for other countries;

- will reduce errors regarding symbols and increase the usability of medical devices;

- will avoid uncertainty and misinterpretation of the explanatory text adjacent to the symbols if international labeling is used, leading to the request of some countries for translation of this explanatory text although they accept harmonized symbols.

EUROM VI Medical Technology would appreciate if the latest revision of the International Standard ISO 15223:2012 “Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements” and the symbols contained therein would be recognized by the FDA in a first step as this International Standard contains the most commonly used and worldwide understood and accepted symbols for medical devices.

In order to avoid any misinterpretation regarding the requirement that the symbols glossary containing all symbols used on a medical device and their explanations shall “contemporaneously accompany” the corresponding medical device, we would appreciate if this requirement would be explained in more detail or one or more example(s) be provided in the Final Rule. We currently assume that the Instructions for Use are the most suitable location for the symbols glossary.

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EUROM VI is the committee for Medical Technology within the European Federation of Precision Mechanical and Optical Industries and represents mainly European small and medium-sized enterprises.

The objectives of EUROM VI are:

- to represent European Medical Technology Industry;
- to promote cooperation between members but also with other European organisations;
- to encourage worldwide trade by being involved in harmonisation of legislation, standardisation, mutual recognition and certification procedures;
- to be a partner on works with the European Commission and Standardisation Bodies;
- to promote European Industry views in international activities.