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ALERTS

Food, Drug And Device Law Alert - FDA Publishes Final Rule On Use Of Stand-Alone Symbols In Medical Device Labeling

June 27, 2016 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The Food and Drug Administration (FDA) recently issued a final rule on the use of stand-alone symbols (i.e., symbols not accompanied by explanatory text) on labels and in other labeling for medical devices, allowing stand-alone symbols in certain circumstances. The medical device industry had asked the FDA for the ability to use stand-alone symbols on domestic device labeling, consistent with their current use on devices manufactured for European and other foreign markets.

The final rule seeks to harmonize the U.S. device labeling requirements for symbols with international regulatory requirements, such as the Medical Device Directive 93/42/EEC of the European Union (EU) and global adoption of International Electrotechnical Commission (IEC) standard IEC 60417 and International Organization for Standardization (ISO) standard ISO 7000–DB that govern the use of device symbols in numerous foreign markets.

The final rule provides medical device manufacturers with the option to use symbols established by standard-development organizations (SDO) in labeling to communicate information to end users. Under the final rule, manufacturers will be allowed to substitute a label containing stand-alone symbols for other labels that contain written statements only or symbols with adjacent explanatory text, provided that the stand-alone symbols are established by an SDO and as long as one of the following conditions is met:

1. The standard is recognized by FDA and the symbol is used according to the specifications for use of the symbol set forth in FDA's recognition; or
2. if the symbol is not included in a standard recognized by FDA or the symbol is in a standard recognized by FDA but is not used according to the specifications for use of the symbol set out in the FDA recognition, the device manufacturer otherwise determines that the symbol is likely to be read and understood by the ordinary individual under customary conditions of purchase and use and uses the symbol according to the specifications for use of the symbol set forth in the SDO-developed standard.

In addition, in either case, the symbol must be explained in a written or electronic symbols glossary that is included in the labeling for the medical device. Furthermore, according to the new rule, the labeling on or within the package containing the device must bear a prominent and conspicuous statement identifying the location of the glossary that is written in English or, in the case of articles distributed solely in Puerto

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Rico or in a territory where the predominant language is one other than English, the predominant language may be used. The use of such symbols must also comply with other applicable labeling requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act, such as sections 502(a) and 502(f).

In addition, the final rule allows the use of the symbol statement ‘‘Rx Only’’ or ‘‘? Only’’ for labeling of prescription devices.

A copy of the Federal Register Notice for the final rule can be found here.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm’s Food, Drug & Device Group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; or Alicia Raines Barrs at (317) 231-7398 or alicia.rainesbarrs@btlaw.com.