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ALERTS

Food, Drug & Device Law Alert - FDA Issues Proposed Rule To Allow Use Of Stand-Alone Symbols On Medical Device Labels

May 7, 2013 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently issued a proposed rule to allow the use of stand-alone symbols (i.e., not adjacent to a text explanation) on the labels of medical devices. Under the current regulation, 21 C.F.R. 801.15, graphics, pictures, or symbols in labeling that represent required information must be accompanied by explanatory English text adjacent to the symbol in order to "appear thereon in the English language." The proposed rule would allow use of recognized symbols without explanatory text under certain circumstances.

The medical device industry had asked FDA for permission to use stand-alone symbols in device labeling, offering two rationales. First, symbols would make labels more user-friendly by replacing small, difficult-to-read text with pictorial information. Second, allowing the use of stand-alone symbols would harmonize the labeling requirements of U.S. and foreign regulatory agencies. In response, FDA is proposing to revise several regulations to expressly allow for the use in medical device labeling of certain stand-alone symbols that are permitted in Europe and elsewhere.

Under the proposed rule, the symbols can be used under two conditions. First, the symbols must be contained in a standard that FDA recognizes under the Food, Drug & Cosmetic (FD&C) Act. Internationally, voluntary standards such as ISO 15223 have standardized, commonly-used symbols that are often used in U.S. device labeling with adjacent explanatory text, and in limited instances, without adjacent text for in vitro diagnostic devices. FDA states that it will maintain a list of approved symbols on its website (which already includes a list of recognized standards).

Second, a "symbols glossary" must contemporaneously accompany the device. The term "symbols glossary" means a compiled listing of each symbol used in the labeling of the device and of the meaning of or explanatory text for the symbol.

The proposed rule will also continue to allow the use of symbols, including standardized symbols, on device labeling when the symbols are accompanied by explanatory adjacent text.

FDA is accepting comments on the proposed rule until June 18, 2013. A copy of the Federal Register announcement of the proposed 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

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