SYMBOL-ONLY SAFETY LABEL FORMATS GAIN NEW GROUND

By Geoffrey Peckham

This month in our series exploring the latest industry insight on effective product safety label design and symbol usage, we'll focus on the United States Food and Drug Administration's (FDA's) approval of symbol-only safety labels – and how the path is being paved for worldwide approaches to "wordless" safety labeling.

I'm going to use this final article in this year's *On Your Mark* series on symbols to focus on a significant development in the standards landscape that merits your attention. In June of this year, the FDA approved the use of symbol-only safety label formats. Read on to learn how this groundbreaking regulation signals a shift in the future of safety communication, both in the U.S. and worldwide, for all types of products, not just medical devices.

THE FDA'S NEW RULE

The FDA's final rule on the "Use of Symbols in Labeling" was published in the Federal Register on June 15, 2016, to go into effect 90 days thereafter.[1] Per the new rule, the FDA now "explicitly permits the use of symbols in medical device labeling without adjacent explanatory text if certain requirements are met." The rule stipulates that a stand-alone symbol can be used if the symbol was established as part of a standard written by a national or international standards development organization such as the American National Standards Institute (ANSI) or International Organization for Standardization (ISO) (both standards-writing organizations recognized by the FDA). The FDA rule also allows device manufacturers to use symbols that are not included in recognized standards if the manufacturer can determine the symbol is likely to be read and understood by their device's audience. To assist in the comprehension of new and standardized symbols, the FDA requires there to be an accompanying symbols glossary (in paper or electronic form); a statement identifying the location of the symbols glossary has to be included prominently in the medical device's "labeling" or packaging.[2] The medical device industry had requested the FDA to make a ruling to allow the use of stand-alone symbols on domestic device labeling so labeling could be consistent for devices sold both in the U.S. and abroad. Symbol-only formats, such as depicted in Figure 1, have gained acceptance in many regions of the world.

Essentially, the FDA is harmonizing label requirements for the U.S. device market with accepted symbol-only formats currently allowed by international standards, such as European Norms, International Electrotechnical Commission standards, and ISO standards.

SYMBOL COMPREHENSION AND LEGIBILITY

The use of symbol-only safety label formats has, over the past decade, become more and more widespread as manufacturers turn to using ISO and IEC standards for a global approach to safety labeling. To a degree, there are issues concerning symbol comprehension and legibility; both are complex issues. Symbols included in ISO and IEC standards are typically designed to established design rules that enable the symbols to have a degree of consistency and allow them to be "legible," even when used in small sizes. But to assure "comprehension" of a symbol is another matter. Who, exactly, is the intended audience for the symbols in question? Are they trained professionals

1. At the time of writing, the rule was set to go into effect 90 days from the June 15, 2016 publication date.

2. Of note here is that the term "labeling" is used by the FDA in a wider sense to mean writing or printing included with the medical device's packaging, container or wrapping. As stated in Section II Comments on the Proposed Rule and the FDA's Response in subsection E regarding the symbols glossary requirement, the symbols glossary could be provided in the package insert, as a separate insert within the package, on the side panel of the package, or electronically at the manufacturer's website.

or the general public? Do the intended viewers have an opportunity to be exposed to symbol-only safety labels on a repeated basis? Or will such formats be rarely seen by the intended audience in their daily lives and/or work experience? Adding to the complexity of the question of symbol comprehension is that different people have different learning characteristics, which means different abilities to learn "visually." Will the intended audience be able to "learn" the meaning of your symbols? So, as you can see, assuring comprehension of new or standardized symbols is next to impossible. It's for this reason that ISO and IEC standards do not make symbol comprehension a requirement for symbols being standardized.

In light of this, I believe the FDA got it right when it stated that device manufacturers should use symbols that have been standardized by official standards bodies and that they did not require manufacturers to prove that the symbols they use are understandable. Instead the FDA has manufacturers point viewers to a glossary of symbol meanings because symbols cannot always be intuitively understood. One of the core tenants of international graphical symbol standardization is that through widespread use, symbols will become more widely understood. Thus, consistent use of "established," standardized symbols for established meanings will, in time, help symbols to become intuitively understood. If, on the other hand, manufacturers individually created their own different symbols for specific functions or meanings, you can see how the result would be chaos for viewers. So, again, the FDA got it right – use standardized symbols whenever possible. In the end, this will promote worldwide comprehension of medical device labels.

Figure 1: Examples of symbol-only "no text" safety label formats: at left, a label on a scooter taken in Italy; at right, labels on consumer products (a portable sander, at top, and a chainsaw, at bottom) in the U.S.

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THE FUTURE – AND CONVEYING YOUR SAFETY MESSAGE

As we discussed in the April article in this year's series, the world is trending towards graphic-based safety label design where symbols are used to convey all aspects of a label's content. In safety labeling, this most often means the label's symbols convey the nature of the hazard, the consequence of interaction with the hazard, and actions to take (or not to take) to avoid the hazard. The FDA's acceptance of symbol-only, wordless formats reinforces this direction in safety labeling. As the world moves towards labeling that is independent of words, the need for translations appearing on labels will also become a thing of the past.

As of the writing of this article, the ANSI and ISO standards committees in charge of the principle standards for product safety labeling (ANSI Z535 and ISO 3864, respectively) are looking at various approaches to "wordless," symbol-only formats for possible inclusion in future revisions of these standards. Wordless safety label formats exist in the ISO standards, and the ANSI Z535 standard for product safety labeling (ANSI Z535.4) allows manufacturers to use the ISO standards for their safety label formats – which is a round-about way of accepting the use of symbol-only formats. In time, the ANSI standard may include one or more wordless formats, or it may just continue referring readers to the use of ISO standards. In either case, I believe that having regulatory bodies like the FDA establish rules for labeling that endorse the use of "wordless" safety label formats will make wordless product safety labels the norm for many industries' products.

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