



APA Statement on the Use of Color Coding

This statement is in response to the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) announcement of a public hearing on the current practice of applying color to pharmaceutical product packaging and labeling to help identify, classify, and differentiate those drug products. Specifically, the FDA has asked for comments addressing the following issues:

- How and under what circumstances has the use of color on pharmaceutical packaging and/or labeling demonstrated an improvement in patient care? If there is no discernible improvement, please describe what you consider to be deficiencies in the program.
- Are there specific classes of drugs where use of color has demonstrated value? Are there classes where use of color is a hindrance to public safety?
- Are there drug products currently marketed that do not use color but should use color to aid in identification of the drug? If so, how should color be used?
- How should the effectiveness of application of color on drug products be scientifically validated?

There has been a good deal of research on color as a factor in safety communications (warnings), and there are relevant guidelines such as the ANSI Standard for product warnings (ANSI Z535). There is also a history of color coding medications by dosage levels, so there is a sort of precedent in that regard. Color can be an important for quick recognition of a container's contents. For example, bottles of contact cleaner and eye drops are nearly the same. Distinctive colors on the label or cap could provide a cue before contact cleaner is dropped into the eyes. Color might also be used to enhance the conspicuity of significant information and perhaps to code the level of importance of the information. This has the potential to help reduce errors. However, there are problems with this approach for many reasons. First, individuals who are color blind may be unable to detect the differences between the colors. Second, it is not clear how these guidelines might be set up across manufacturers. If each manufacturer uses a different color coding scheme, much of the potential benefit would be lost. Third, there is a need to consider the contrast and saturation of the colors used, as well as the pattern of the coloration, and how color is being used as a redundant or adjunct cue. Finally, there is no empirical evidence showing that color has provided the potential benefits proposed. We are not aware of literature or guidelines on the use of color specifically for pharmaceutical packaging or labeling. This topic area is fairly controversial in medicine. The American Society of Health-System Pharmacists (ASHP), the Institute for Safe Medication Practices (ISMP), the USP, and the pharmaceutical industry generally either oppose color coding or recommend caution in its application, probably for the reasons cited above.

Controlled research on the use of color in surgery suggests that it is not useful. Specifically, the inclusion of color in image-guided interventions has been proposed as beneficial (Bucholz, Sturm, & Hogan, 1998). However, human-factors research showed that benefits of color are dependent on specific task parameters, and that color requires additional processing time, which results in slower reaction times (Wickens & Andre, 1990). In some cases, such as virtual endoscopy, color information has been shown to be misleading (Blezek & Robb, 1997).

We would recommend that the effectiveness of the application of color on drug products be scientifically validated prior to authorizing its use for that purpose. Determining effectiveness would require experimental studies comparing the performance of users interacting with drugs labeled with or without color cues. These studies would have to be conducted with users who are representative of the range of users likely to use the products and they would have to be labeled with a range of colors and patterns that

are representative of the colors and patterns likely to be marketed. However, controlled laboratory studies would represent only the first step in such research. It would remain important to understand how effective color is in the real world, including studies that look at variations in characteristics such as the physical environment (e.g. lighting), variations in user knowledge (e.g., physicians, nurses, the public), as well as constraints on the time available to cross-check the medication required against that which is selected. Without controlled laboratory studies in conjunction with clinical trials and the collection of errors made over time, it will not be possible to firmly establish the benefits and dangers associated with the use of color for pharmaceutical product packaging and labeling.

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