

First, allow us to share a general comment. Clearly, we live in a world of color. Color is used all around us and consumers are accustomed to color in print media (including magazines and newspapers), internet sites, television, movies, and video, and even the menus on cellular telephones. Therefore, color is now and should continue to be one “tool in the toolbox” to facilitate informative communication between one party (in this case, a prescription drug manufacturer) and the audience (in this case, health care professionals and patients/consumers). In the paragraphs below, we will summarize some of the unique considerations, from our experiences, that merit use of color in labeling of prescription drug products.

Patient-Directed Labeling

The option to consider use of color has been valuable in preparing patient-directed labeling. We will briefly describe two examples.

- Relenza® (zanamivir for inhalation) is an antiviral drug product for the treatment of influenza in selected patients. Relenza is administered via inhalation from the Diskhaler hand-held inhaler. Many patients who are candidates for Relenza have no prior experience with inhalation products. Therefore, we developed written instructions for use, for the patient, as part of labeling for the product. This labeling was approved by the Division of Antiviral Drug Products as part of the original NDA. Importantly, use of color in these instructions for patients added visual clarity to the labeling and, in our view, increased the likelihood that consumers would understand the instructions.
- Imitrex® has an injectable formulation of sumatriptan (the Imitrex STATdose System) for treatment of migraine. Proper use of this product, particularly in the context of the symptoms associated with migraine, requires careful attention by the patient to instructions in labeling on use of the auto-injector. GSK prepared patient-directed instructions for use, including color components, which are approved as labeling and packaged with this prescription drug product. These instructions are made more informative and consumer-friendly by use of color, including color illustrations.

These are only two examples, of a number of available examples, where the need for clear communication and consumer friendliness for patient-directed instructions for use of prescription drug product can benefit from the option to use color in labeling.

Medication Guides are another type of patient-directed labeling that can benefit from the option to use color. Color has been used to facilitate version control of Medication Guides for various products. Color-aided version control can be particularly helpful to pharmacists and patients. As you know, the patient is encouraged to read the Medication Guide each time a prescription drug is refilled since there may be new or revised