

April 6, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: [Docket No. 2005N-0036]
Use of Colors on Pharmaceutical Labeling/Packaging

Dear Sir/Madam:

Baxter International Inc., through its subsidiaries, assists health-care professionals and their patients with the treatment of complex medical conditions, including cancer, hemophilia, immune disorders, kidney disease and trauma. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives.

In the past, pharmaceutical companies along with CDER review divisions have agreed to the use of colors to highlight specific information or to distinguish one item from another. Baxter uses colors for drug/device matching in surgical settings (color matching). Baxter also uses colors on pharmaceutical labeling and packaging to enhance the labeling/packaging (color differentiation). Colors are used to focus attention on important information and to highlight steps to follow necessary in assuring the proper dosing of the product. Color coding on the other hand is the systematic standard application of designated colors on the labeling of specified drug products to assist health care providers and consumers in product classification and identification.

Baxter has worked with the Institute for Safe Medication Practices, to assure that the labeling of our products helps in minimizing medical errors. Baxter has convened a Color Committee to evaluate the use of colors in labeling/packaging. Focus groups have been assembled to evaluate the usefulness and effectiveness of drug labeling and packaging for Baxter drug products.

Baxter applauds the Food and Drug Administration (FDA) for seeking public input on the benefits or drawbacks from applying color to pharmaceutical product packaging and labeling to help identify, classify and differentiate those drug products. Baxter welcomes the opportunity to share our experiences and to participate in this information gathering effort, and wishes to offer the following comments for consideration.

General Comments

Baxter's position is that labeling and packaging should be reviewed and evaluated in its entirety during the drug and medical device approval process. It should be an interactive process between the sponsor and each FDA reviewing division, taking into account the unique aspects of each drug product. Baxter does not support the use of color coding to aid in the classification and identification of all drug products. Color is only one aspect that is applied to help identify and differentiate drug products and to highlight important information. Other tools are available to help such as type size, font, location of information and the labeling content. We do support the use of color coding in very limited and specific settings where the use of color coding is likely to result in a decrease of medical errors. An example is the established practice of using colors for different classes of drugs routinely used by anesthesiologists during surgery.

If you have any questions, please contact me at (301) 977-7795. Thank you for the opportunity to share Baxter's views with you.

Sincerely,

Marie A. Urban
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