



April 7, 2005

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

Re: **Docket No. 2005N-0036**  
**Use of Color on Pharmaceutical Product Labels, Labeling and Packaging;**  
**Public Hearing**

Dear Sir/Madam:

The following comment is being submitted by Apotex Inc. further to the publication of Docket No. 2005N-0036 regarding the Use of Color on Pharmaceutical Product Labels, Labeling and Packaging published in the Federal Resister on February 3, 2005.

Apotex Inc. is not in favor of color coding of drug product labeling for the following reasons:

- Color coding may promote or result in reliance by pharmacists, patients and medical staff on the color for product identification, rather than reading the label, potentially resulting in an increase in medication errors
- The use of bar coding should be emphasized as a key identification feature rather than color
- Color coding may actually increase potential dangers for color blind users
- The spectrum of colors required to code all drug products and the control measures required to ensure exact color application would be excessive. In addition, the greater number of colors used could potentially create more confusion than less for products very close in color.

For these reasons, Apotex Inc. does not recommend implementation of a universal color coding system for product labeling. However, Apotex does believe there may be specific drug products or certain classes of drugs where color coding may be beneficial, such as ophthalmics, when the number of products coded is limited and there are inherent difficulties in reading labels due to their small size.

Apotex Inc. does agree with voluntary use of color differentiation as a means to heighten awareness of pharmacists, patients and medical staff of differences between products or among product lines for the following reasons:

- Color differentiation can help to distinguish between various strengths and/or pack sizes of a particular product potentially resulting in fewer errors when the strengths and/or pack sizes would otherwise all look very similar in appearance
- Color differentiation can help to distinguish between drug products that may have look-alike or sound-alike names, or are similar in some other characteristic that has a higher potential to cause medication errors
- The colors used do not have specific meaning and are not standardized in the industry; therefore, one cannot rely on the color but must read the label to select the correct drug product

The following are examples of circumstances where the use of color differentiation on pharmaceutical packaging and/or labeling has demonstrated an improvement in patient care:

**Hospital and Pharmacy Settings:**

- Color can function as an extra identifier when a pharmacy technician is pulling multiple vials of the same medication from a storage bin, and one vial cap does not match the others, it will immediately draw attention to that particular vial. The vial might have otherwise been overlooked for the simple fact that the technician is pulling the medication under the assumption that all the vials in the properly marked bin are the same. This can be particularly important when the same drug, but in different strengths, are placed right next to each other.

This fact is not undermining the importance of checking the name because there is more than one type of medication with the same color vial top. For example, a manufacturer of Drug A produces a vial with a yellow top, as does a manufacturer of Drug B.

- Manufacturers of inhaled medications have used the same concept to differentiate between different concentrations. This can be helpful for professions such as nursing and respiratory therapy who may not have the same vigilance for organization and storage as pharmacies.

Retail Pharmacy Settings:

- Retail pharmacies often use color differentiation to help with their storage.
- Many generics are available and often times multiple products from the same company are in the same area of the shelves so color differentiation helps to break up and draw attention to the individual products. For example, our company, Apotex Inc. uses a specialized labeling system to differentiate our various drug products and strengths. We have received feedback through a solicited feedback form from our buyers and pharmacists who use our products saying that our packaging is “perfect packaging”. This system is preferred by Apotex as it provides all of the above-mentioned benefits of color differentiation (i.e., primarily that it draws attention to product differences) without the negative aspects of color coding (i.e., primarily that it fosters reliance on color to identify products as opposed to the label text and bar code).
- Pharmaceutical companies also use color to help tall man lettering stand out.

Should you have any questions or concerns regarding the above, please do not hesitate to contact me at (416) 401-7690 or by e-mail at [jdochert@apotex.com](mailto:jdochert@apotex.com)

Sincerely,

Jennifer Docherty  
Manager, Regulatory Affairs Strategy & Intelligence