



April 6, 2005

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

RE: DOCKET NO. 2005N-0036

Dear Sirs:

We are pleased to have the opportunity to comment on Docket 2005H-0036, Use of Color on Pharmaceutical Product Labels, Labeling and Packaging. Colorcon representatives attended the March 7 public hearing on this topic and we are in agreement with many of the speakers at the hearing in our opinion that the use of color to identify therapeutic categories generally (color coding) may be limited in its utility to reduce medication errors. However, we do believe that substantial progress in the reduction of medication errors could be attained from the use of color, on the drug packaging and labeling as well as on the drug product itself, in the case of solid oral dosage forms, as a means to complement the product labeling and thus aid in drug identification. Our comments that follow focus on the use of color on drug packaging, labeling and drug products in the context of color branding and color differentiation, as defined in the Federal Register Notice.

Using Color in drug Packaging and Labeling
FDA Questions
Colorcon Brand Enhancement Services Comments to FDA

1. How and under what circumstances has the use of color on pharmaceutical packaging and / or labeling demonstrated an improvement in patient care?

The following comments relate to regulatory action that has been taken by the states of California, Oregon and Wyoming to require the identification of the pill in terms of its: 1) Color, 2) Shape and 3) Imprint Logo or Code on the package (vial) label. The purpose of this legislation was to reduce medication errors by employing color, as one of 3 key drug identification elements, of the pharmaceutical product, i.e. color on-tablet and on-package/ label.

- a. Published by the Legislative Counsel's Digest on February 19, 2003 (from which legislative comments in this document are referenced), the certain states of Oregon and Wyoming have regulated that prescription labels must include a physical description of the drug (which includes color as well as pill shape and imprint code) on the container labels. The Oregon State Board of Pharmacy promulgated the requirement effective July 1,

2000. Wyoming required the prescription label to also include the descriptions of the drug (color, shape, imprint code) effective January 1, 2004.

- b. It is reported as a comment to the legislation published in conjunction with California Senate Bill Number SB 292 that "The staff at that Board (Oregon State Board of Pharmacy) also indicated that this (the inclusion of physical description of the pill color, shape and imprint code on the prescription vial label) seems to have been a worthwhile endeavor and has been helpful in preventing medication errors."
- c. The following are selected comments published in conjunction with California Senate Bill Number SB 292 which was passed in the Senate on September 9, 2003: "This bill: Requires, as of January 1, 2006, prescription labels to include a physical description of the tablet or capsule of the drug. This description is to include the color, shape, and any identification code that appears on the tablet or capsule."

- i. "Comments:

- 1. Purpose. According to the author, this bill will reduce the number of errors made in the administration and consumption of prescription medication. In addition to pharmacy error, SB 292 addresses confusing and potentially dangerous situations in which pills are disassociated from their bottles. Such a situation may occur by accident or by design. A patient may spill more than one container of drugs and mix the pills when refilling the bottles or a patient may place her pills in daily dispensers. Patients who are not absolutely sure of the indications for their medication need to refer back to their bottles for confirmation of dosage, timing, side-effects, or conflicts with other drugs. Those taking several medications at a time may be especially at risk of confusing one drug with another. Also, when pharmacists switch from branded medication to generics, the change in pill shape, color, and imprint may mislead the patient used to taking a certain drug. A verbal description of the medication, including its shape, color, and imprint code provides an easy way for patients to make sure that the medication that they are taking is the medication that was prescribed for them, and allows them to associate vital safety information from the label with the correct pills."
 - 2. Are there specific classes of drugs where the use of color has demonstrated value? Across all classes of drugs, there is demonstrated value. What can be done to reduce medication error and enhance compliance with color across all classes of drugs? Color (along with shape and imprint code) of the solid dose

form, on-label and on-package can reinforce the drug identity to the patient, the pharmacist and the care giver. As pointed out in Question / Comment # 1 above, this has been linked by Boards of Pharmacy to reduced medication error and resulted in legislation that links the tablet appearance (color, shape and imprint code) to the label (via physical color, shape, and imprint code description of the solid dosage form). For most prescription drugs the vial and the label constitute the "physical package" in the United States.

The consistency in the use of color on the solid dose form along with the application of the same color on innovative packaging, such as for Dosing Regimen Compliance Packaging, would also provide similar drug recognition for the patient and result in medication error reduction benefits. Consistent color use on-tablet / on-label / on-package would reinforce the identification / recognition of the drug. The combination of color use on compliance packaging and on-tablet would not only reduce medication error, but also enhance patient compliance.

Color recognition between specific drug dosage strengths can be an aid to the pharmacist in reducing medication errors that can result when filling prescriptions. So, color can be used to help identify a drug, and also to help identify dosage strengths of a drug (which is further enhanced by adding the tablet design variables of tablet shape and imprint code).

Color recognition is essential to patient compliance in the identification of pill. A study entitled, "Improving Medication Compliance Through the Use of Modern Dosage Forms" was published by the Journal of Pharmacy Technology, July 1986. This study concluded that pill color (and shape and size) are key to patient recognition / compliance. Visual impairments of the elderly prove it essential to employ as many differentiating sensory features as possible into a tablet design. Certainly, if color is impactful in drug identification and therefore patient compliance, the application of color in drug packaging and labeling only enhances these benefits.

The use of color (and other key overt and covert identification aids) should be used by all drugs to make it difficult for a counterfeiter to fake a solid dose drug while making it easy to identify by the patient, pharmacist, and regulatory bodies. The easiest drug to fake is a plain white round tablet. The most difficult tablet to identify is a plain white round tablet. Therefore, plain white round tablets can negatively impact patient safety by contributing to medication error and counterfeit products. Alternatively, the use of color and other key overt and covert identification aids on the tablet and on the package and on the label can serve to enhance patient safety by reducing medication error and helping to prevent counterfeits.

3. 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?
 - a. Throughout the world, there is a significant percentage of solid dosage forms that are white or do not use color (non-descript with regard to color and pill shape). Although the trend toward tablet design is prevalent (employing color film coatings along with shape and imprint codes / logos for identification), older drugs, even in the United States, are currently marketed that do not use color on-tablet or on-label / vial-package to aid in identification. Additionally, most white tablets are not easily distinguishable by shape, but rather dependent upon debossed inscriptions or imprint codes. Consequently, to improve patient and caregiver identification of the drug to reduce medication error, the use of color (in combination with shape and inscriptions or imprints) is a key essential element in the design of the dosage form. The California Senate Bill Number SB 292, referenced below links the color / shape / imprint code of the solid dosage form to the label. The label should specify the color, shape and identification code of the drug.
 - b. The following are selected comments published in conjunction with California Senate Bill Number SB 292 which was passed in the Senate on September 9, 2003:
 - i. "Background. The author cites numerous studies that have found high rates of medical errors in hospital settings as well as increases in medical errors in outpatient settings. Patients themselves are often not an effective safeguard against medication error. Approximately 7,000 deaths per year in the U.S. are attributable to prescription errors."
 - ii. "Extent and effect of prescription errors."
 1. "The Campaign for Patient Safety conducted an analysis of drug dispensing errors that were reported to the California Board of Pharmacy between June 1997 and March 2000. The analysis shows that by far the largest results of dispensing error were either that the wrong pill was in the right bottle or that the right pill was in the wrong bottle. Although the sample size of the analysis was small (193 total errors were reported to the Pharmacy Board), the Campaign for Patient Safety notes that most pharmacy errors are never reported or scrutinized. The CPS analysis indicates that patients are at risk of unwittingly taking the wrong drug even after consulting with their pharmacist."
 - iii. "Other States with a Similar Requirement in Place."
 1. "In Oregon, pharmacists must print a physical description of drugs on their container labels. This rule, promulgated by

the Oregon State Board of Pharmacy, has been in place since July 1, 2000. Although a pharmacist may print a picture of the drug to satisfy this rule, according to the Oregon Board, most companies choose to print the physical description (ex. "round white tablet" along with the imprint code) on the label. The staff at the Board also indicated that this seems to have been a worthwhile endeavor and has been helpful in preventing medication errors."

2. "Additionally, effective January 1, 2004, Wyoming will require prescription labels to include a physical description."
- iv. "Prior Version of the Bill." SB 292 previously required that all prescription labels include a color image of the drug. Proponents believe that this bill would help reduce the number of medication errors and improve patient safety in California. Having a physical description of the medication on the label will help consumers to determine if they are taking the correct medication. With prescription errors resulting in deaths and hospitalization for thousands, supporters of this bill believe that SB 292 will provide assistance to the consumers of California."
 1. The prior version of the bill SB 292, which required that all prescription labels include a color image of the drug is an "enhanced recognition" feature for patients vs. simply describing the shape, color and imprint logo. Certain logos are simply easier to depict as images vs. descriptions. Also, an image is universally interpreted correctly, whereas the written descriptor may be misunderstood or misinterpreted. Commercial databases of tablet images (color, shape, logo/inscription) to help identify drugs for pharmacies, law enforcement and medical emergency response exist. Similar databases could potentially be employed to provide solid dosage imaging on prescription vial labels and packaging.
4. How should the effectiveness of application of color on drug products be scientifically validated?
 - a. The 5 years of experience by the Oregon State Board of Pharmacy in the prevention of medication errors, resulting from the inclusion of a physical description of drugs on the container labels, should be used as a "practical in-use measure" (in addition to a scientifically validated study) of the effectiveness of the use of on-tablet color linked with on-label color / package color, for drug identification aid and medication error reduction for patients, pharmacists and care givers. Similar considerations of "in-use

measure" should be given to the states of Wyoming and California (beginning in 2006).

- b. Colorcon Brand Enhancement Services would like to request a meeting with the Director, Division of Medication Errors and Technical Support, CDER to present information and research options to validate medical benefits derived by the patient through the use of color on-tablet and on-package.

Sincerely,



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